

US3642081 (Prod: University of California San Diego)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:14:06

All time stamps listed in this document are displayed in GMT

US3642081

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

Participant ID

US3642081

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

US3642081

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3642081

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	68
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input 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

US3642081

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Date of Informed Consent (<i>dd MMM yyyy</i>)	2 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

US3642081

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3642081

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Were any significant conditions reported?

Yes ☒
No ☐

US3642081

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Condition	BREAST CANCER
Start date (dd MMM yyyy)	UN UNK 1982
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3642081

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Condition	HYPERCHOLESTOLEMIA
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)	

US3642081

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Condition	VITAMIN D DEFICIENCY
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)	

US3642081

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3642081

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Condition	RIGHT CATARACT
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3642081

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Condition	RIGHT CATARACT SURGERY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3642081

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Condition	LEFT CATARACT
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)	

US3642081

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:58 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:58
Height (<i>xxx.x</i>)	165 cm
Weight (<i>xxx.x</i>)	62.1 kg
BMI (<i>xxx.x</i>)	22.80992 kg/m ²
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)	

US3642081

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3642081

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*) 02 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

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

US3642081

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:40:41

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

US3642081

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 189495

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 ☒

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Height	ND - Not Done
Weight	ND - Not Done

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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)	02 SEP 2020
Time of assessment (00:00-23:59)	13:58 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:58
Temperature (xxx.x)	99.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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)	02 SEP 2020
Time of assessment (00:00-23:59)	16:22 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 16:22
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3642081

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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.

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 15:39 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 15:39

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

What was the frequency of the study treatment dosing? ONCE

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

US3642081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 SEP 2020
Collection time (00:00-23:59)	15:00 (24 HR)
Collection date and time (derived)	02 SEP 2020 15:00

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:55	02 SEP 2020 14:55
Nasopharyngeal Swab 2	No		

US3642081

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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

97.9 °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

02 SEP 2020 16:02

PC Open Date & Time

02 SEP 2020 15:59

PC Close Date & Time

02 SEP 2020 18:29

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 02 SEP 2020 19:24

PC Close Date & Time 03 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

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

98.2 °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

03 SEP 2020 16:00

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

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

04 SEP 2020 15:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 15:32

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 14:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

07 SEP 2020 14:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 13:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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

02 SEP 2020 16:03

PC Open Date & Time

02 SEP 2020 15:59

PC Close Date & Time

02 SEP 2020 18:29

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

02 SEP 2020 19:24

PC Close Date & Time

03 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

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

03 SEP 2020 15:16

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

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

04 SEP 2020 15:10

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

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

05 SEP 2020 15:33

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

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

06 SEP 2020 14:23

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

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

07 SEP 2020 14:11

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

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

08 SEP 2020 13:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 16:04
PC Open Date & Time	02 SEP 2020 15:59
PC Close Date & Time	02 SEP 2020 18:29

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 19:24

PC Close Date & Time

03 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 15:17
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 15:10
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 15:33
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 14:24
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 13:23
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3642081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 23:28:15

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	VISIT2

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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)	01 OCT 2020
Time of assessment (00:00-23:59)	14:47 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 14:47
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)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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)	01 OCT 2020
Time of assessment (00:00-23:59)	16:55 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 16:55
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3642081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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 OCT 2020

What was the treatment time? (00:00-23:59) 16:25 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 16:25

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

US3642081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 OCT 2020

Collection time (00:00-23:59)

16:04 (24 HR)

Collection date and time (derived)

01 OCT 2020 16:04

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:06	01 OCT 2020 16:06
Nasopharyngeal Swab 2	No		

US3642081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 16:46

PC Open Date & Time

01 OCT 2020 16:45

PC Close Date & Time

01 OCT 2020 19:15

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 97.6 °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	01 OCT 2020 21:17
PC Open Date & Time	01 OCT 2020 20:10
PC Close Date & Time	02 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

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

98.7 °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 02 OCT 2020 16:05

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 16:23

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 OCT 2020 02:33

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 15:24

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 OCT 2020 18:44

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

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

98.7 °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

08 OCT 2020 09:40

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 OCT 2020 16:47

PC Open Date & Time

01 OCT 2020 16:45

PC Close Date & Time

01 OCT 2020 19:15

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

01 OCT 2020 21:18

PC Open Date & Time

01 OCT 2020 20:10

PC Close Date & Time

02 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 OCT 2020 16:06

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 OCT 2020 16:23

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

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

05 OCT 2020 02:33

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 OCT 2020 15:24

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 OCT 2020 18:45

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

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

08 OCT 2020 09:40

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 16:48
PC Open Date & Time	01 OCT 2020 16:45
PC Close Date & Time	01 OCT 2020 19:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 21:19
PC Open Date & Time	01 OCT 2020 20:10
PC Close Date & Time	02 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 16:06
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 16:24
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 02:34
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 15:25
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 18:45
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

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 ☒

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 09:40
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3642081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:41 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 13:41
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	56 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

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.

US3642081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 OCT 2020

Collection time (00:00-23:59)

14:10 (24 HR)

Collection date and time (derived)

30 OCT 2020 14:10

US3642081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:41

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 18:00:22

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

10 NOV 2020 18:57:16

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

16 NOV 2020 06:44:38

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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	27 NOV 2020 08:00:51
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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	04 DEC 2020 02:35:34
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

11 DEC 2020 05:33:00

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

18 DEC 2020 07:41:48

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 DEC 2020 08:27:51
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 06:25:44

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 03:42:11
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 18:42:24

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

22 JAN 2021 00:01:31

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	01 FEB 2021 18:54:46
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 05:04:48

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 04:32:23

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

22 FEB 2021 17:59:35

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 10:12:42

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 04:26:51

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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	12 MAR 2021 00:02:50
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

22 MAR 2021 17:59:39

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

26 MAR 2021 07:59:50

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	02 APR 2021 03:16:31
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

09 APR 2021 07:23:37

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

16 APR 2021 16:57:03

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 APR 2021 03:03:51
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

30 APR 2021 02:19:59

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

Patient Cloud Open Date & Time	17 DEC 2021 00:01
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Patient Cloud Close Date & Time	21 DEC 2021 23:59
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US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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°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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 <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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐ Yes ☐

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3642081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:14:06

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		05 MAR 2021 04:27:22

US3642081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

CALL MADE OUT OF WINDOW
D/T STAFF ERROR.

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 01:40:53

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 01:40:53

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 23:28:15

Generated On: 10 Jun 2021 09:14:06

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) _____

US3642081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

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.

US3642081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	15:15 (24 HR)
Collection date and time (derived)	16 MAR 2021 15:15

US3642081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:21:16

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:21:16

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3642081

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:14:06

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3642081

Folder: Covid-19 Assessment (2)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:14:06

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"/>

US3642081

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

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

Visit date (dd MMM yyyy)	16 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3642081

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 02:13:17

Generated On: 10 Jun 2021 09:14:06

Date of updated informed consent (<i>dd MMM yyyy</i>)	16 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

US3642081

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

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

US3642081

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

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)	16 JAN 2021
Time of assessment (00:00-23:59)	10:12 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 10:12
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)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3642081

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

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)	16 JAN 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 11:40
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3642081

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

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

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.

US3642081

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:04:49

Generated On: 10 Jun 2021 09:14:06

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) 16 JAN 2021

What was the treatment time? (00:00-23:59) 11:14 (24 HR)

Treatment Date and Time (derived) 16 JAN 2021 11:14

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

US3642081

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 JAN 2021

Collection time (00:00-23:59)

10:51 (24 HR)

Collection date and time (derived)

16 JAN 2021 10:51

US3642081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00 - 23:59)	10:53
Collection Date and Time (derived)	16 JAN 2021 10:53

US3642081

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

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:40:40

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:04:49

Generated On: 10 Jun 2021 09:14:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Mar 2021 01:40:44

Generated On: 10 Jun 2021 09:14:06

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)	13 FEB 2021
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	13 FEB 2021 10:19
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Mar 2021 01:40:44

Generated On: 10 Jun 2021 09:14:06

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)	13 FEB 2021
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	13 FEB 2021 11:47
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3642081

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:04:49

Generated On: 10 Jun 2021 09:14:06

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.

US3642081

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:04:49

Generated On: 10 Jun 2021 09:14:06

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) 13 FEB 2021

What was the treatment time? (00:00-23:59) 11:07 (24 HR)

Treatment Date and Time (derived) 13 FEB 2021 11:07

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

US3642081

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:04:49

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 01:40:53

Generated On: 10 Jun 2021 09:14:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642081

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 01:40:53

Generated On: 10 Jun 2021 09:14:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642081

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

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) _____

US3642081

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

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.

US3642081

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	15:15 (24 HR)
Collection date and time (derived)	16 MAR 2021 15:15

US3642081

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:14:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

AEID	USA-US109-2021-MRNA-1273-P30 1000012
Adverse event	EPIGASTRIC PAIN
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)	28 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	29 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 2221

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

PATIENT EXPERIENCED SHARP
NON-RADIATING MID
EPIGASTRIC PAIN ON THE
MORNING OF 28MAR2020. SHE
PRESENTED TO THE ER AND
WAS WORKED UP FOR
APPENDICITIS AND ADMITTED
INPATIENT TO A
MEDICAL/SURGICAL UNIT. SHE
WAS MADE NPO, GIVEN IV
ANTIBIOTICS AND HAD AN
ABDOMINAL CT. ABDOMINAL
CT SHOWED PROBABLE
APPENDICITIS BUT DID NOT
WARRANT SURGICAL
INVENTION. BY HOSPITAL
LATE AFTERNOON 29MAR2020
THE PATIENT WAS ABLE TO
TOLERATE A REGULAR DIET,
PAIN WAS RESOLVED, AND
ABDOMINAL ASSESSMENT
WAS BENIGN. SHE WAS
DISCHARGED HOME ON PO
ANTIBIOTICS WITH STRICT
RETURN TO ER PRECAUTIONS
SHOULD EPIGASTRIC PAIN
RETURN. SHE WILL FOLLOW
UP WITH GI IN LATE APRIL2021.
WHILE IN HOSPITAL, PATIENT
UNDERWENT ROUTINE
COVID-19 TESTING ON
29MAR2020. RESULTS WERE
NEGATIVE.

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

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

AEID

Adverse event

SHINGLES INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

358 of 2221

EAB) (1725)

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

SUBJECT REPORTS THAT ON
26JAN2021SHE STARTED TO
DEVELOP A RASH ON HER
BOTTOM. THE RASH PERSISTED
FOR A FEW DAYS, SO SHE
DECIDED TO FOLLOW UP WITH
HER PCP. HER PCP PROVIDED
CONFIRMATION THAT SHE
WAS EXPERIENCING A
SHINGLES INFECTION AND
PRESCRIBED HER
VALACYCLOVIR TO TREAT
THE SHINGLES. THE INFECTION
RESOLVED THE 09FEB2021 AND
SHE HAS HAD NO ISSUES
SINCE.

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)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 02:40:19

Generated On: 10 Jun 2021 09:14:06

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

Yes ☒

No ☐

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

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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

362 of 2221

EAB) (1725)

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	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"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICENCY

Dose per administration 2000

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

364 of 2221

EAB) (1725)

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication MULTIVITAMIN CENTRUM

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

366 of 2221

EAB) (1725)

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	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"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 200

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)

368 of 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHE

Dose per administration 200

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 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS FOR FLU
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 200

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 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 OCT 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication FEVER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

376 of 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication OFLOXACIN 0.3

Prophylaxis Yes ☐
No ☒

Indication LEFT CATARACT SURGERY

Dose per administration 1

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

If dose unit is Other, specify DROP

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 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	LEFT EYE (OPHTHALMIC)	
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication IOHEXOL (OMNIPAQUE 350)

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC PAIN

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

380 of 2221

EAB) (1725)

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 MAR 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 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC PAIN

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)

382 of 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	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)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	29 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC PAIN

Dose per administration 4500

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 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 MAR 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 MAR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication AUGMENTIN

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC PAIN

Dose per administration 875/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

386 of 2221

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	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)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

Name of Medication VALACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication SHINGLES INFECTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

388 of 2221

EAB) (1725)

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 20:50:29

Generated On: 10 Jun 2021 09:14:06

	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)		29 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 FEB 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"/>

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 23:55:48

Generated On: 10 Jun 2021 09:14:06

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 23:28:15

Generated On: 10 Jun 2021 09:14:06

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 MAR 2021	LEFT CATARACT SURGERY	Medical History	
28 MAR 2021	ABDOMINAL CT	Diagnostic	

US3642081

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:14:06

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

US3642081

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:06

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 ☐

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:14:06

SAEID	USA-US109-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:14:06

SAEID	USA-US109-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	05/APR/2021 12:04
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

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:14:06

SAEID	USA-US109-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	14/APR/2021 10:07
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

US3642081 (Prod: University of California San Diego)

US3642081

Form: Participant Creation

Generated On: 10 Jun 2021 09:14:06

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'US3642081'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:34:33

US3642081

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:20

US3642081

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete all applicable forms for this visit.' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 04:39:24
	Megan Loughran (b) (4)	01 Oct 2020 21:08:35
User opened query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4)	
User entered '02 SEP 2020'	(b) (4), (b) (6)	08 Sep 2020 10:55:56
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	02 Sep 2020 21:34:34

US3642081

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:20

US3642081

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'SCRN'	System	02 Sep 2020 22:53:20

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:34:35

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	02 Sep 2020 22:57:50
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:57:50
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	02 Sep 2020 22:54:40
User entered '67'	Megan Loughran (b) (4) (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'YEARS'	System	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '69'	System	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Female (F)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:57:50
User entered 'Male (M)'	Megan Loughran (b) (4) (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'I'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Megan Loughran (b) (4)	02 Sep 2020 22:53:52

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '2 Sep 2020'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Sep 2020'	System	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2020'	System	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Amendment 3 (3)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:54:40

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:34:34

US3642081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'I'	System	02 Sep 2020 22:54:45

US3642081

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 22:54:45

US3642081

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:14:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:49:12

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Sep 2020 17:51:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:51:35
Data point term sent to Coder	System	17 Sep 2020 17:50:13
User entered 'breast cancer'	Son Do (b) (4)	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'UN UNK 1982'	Son Do (b) (4)	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'UN UNK 2015'	Son Do (b) (4)	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 1982'	System	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '1982'	System	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 2015'	System	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2015'	System	17 Sep 2020 17:49:51

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:51:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:51:35
Data point term sent to Coder	System	17 Sep 2020 17:50:13
User entered 'hypercholesterolemia'	Son Do (b) (4)	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'UN UNK 2018'	Son Do (b) (4)	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 2018'	System	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2018'	System	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	17 Sep 2020 17:50:08

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:52:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:52:44
Data point term sent to Coder	System	17 Sep 2020 17:51:14
User entered 'vitamin d deficiency'	Son Do (b) (4)	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'UN UNK 2015'	Son Do (b) (4)	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 2015'	System	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2015'	System	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	17 Sep 2020 17:50:22

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 21:10:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 21:10:53
Data point term sent to Coder	System	01 Oct 2020 21:10:05
User entered 'migraines'	Megan Loughran (b) (4)	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'UN UNK 1990'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 1990'	System	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '1990'	System	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	01 Oct 2020 21:09:34

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 17:05:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 17:05:27
Data point term sent to Coder	System	04 Nov 2020 17:04:43
User entered 'post menopausal'	Son Do (b) (4)	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'I'	Son Do (b) (4)	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	04 Nov 2020 17:04:30

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Mar 2021 22:14:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 22:14:57
Data point term sent to Coder	System	16 Mar 2021 22:13:51
User entered 'right cataract'	Colleen McLellan (b) (4) (b) (4)	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'UN UNK 2015'	Colleen McLellan (b) (4)	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '0'	Colleen McLellan (b) (4)	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'No (N)'	(b) (4) Colleen McLellan (b) (4)	16 Mar 2021 22:13:43
	(b) (4)	

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'UN UNK 2018'	Colleen McLellan (b) (4)	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '0'	Colleen McLellan (b) (4)	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 2015'	System	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2015'	System	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 2018'	System	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2018'	System	16 Mar 2021 22:13:43

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Mar 2021 22:16:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 22:16:02
Data point term sent to Coder	System	16 Mar 2021 22:14:52
User entered 'right cataract surgery'	Colleen McLellan (b) (4) (b) (4)	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'UN UNK 2018'	Colleen McLellan (b) (4)	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '0'	Colleen McLellan (b) (4)	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'No (N)'	(b) (4) Colleen McLellan (b) (4)	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'UN UNK 2018'	Colleen McLellan (b) (4)	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '0'	Colleen McLellan (b) (4)	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 2018'	System	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2018'	System	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 2018'	System	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2018'	System	16 Mar 2021 22:14:15

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Left cataract - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Mar 2021 22:31:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 22:31:04
Data point term sent to Coder	System	16 Mar 2021 22:14:52
User entered 'left cataract'	Colleen McLellan (b) (4) (b) (4)	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'UN UNK 2015'	Colleen McLellan (b) (4)	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '0'	Colleen McLellan (b) (4)	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Colleen McLellan (b) (4)	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '0'	(b) (4) Colleen McLellan (b) (4)	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'Jan 2015'	System	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '2015'	System	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	16 Mar 2021 22:14:36

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '13:58'	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '02 Sep 2020 13:58'	System	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '165' cm	(b) (4)	17 Sep 2020 17:54:03
DataPoint set to visible.	Son Do (b) (4)	02 Sep 2020 22:54:45
	System	

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '62.1' kg	(b) (4)	17 Sep 2020 17:54:03
DataPoint set to visible.	Son Do (b) (4)	02 Sep 2020 22:54:45
	System	

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '22.80992'	System	17 Sep 2020 17:54:03
DataPoint set to visible.	System	02 Sep 2020 22:54:45

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'kg/m2'	System	17 Sep 2020 17:54:03
DataPoint set to visible.	System	02 Sep 2020 22:54:45

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 04:39:15
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:10:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:10:36
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 21:42:42
User entered '99.8' F	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty; reason for change Per Query Resolution	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:10:36
User entered 'Axillary (Axillary)'	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:10:36
User entered '87'	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'bpm'	System	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:10:36
User entered '17'	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'breaths/min'	System	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:10:36
User entered '134'	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:10:36
User entered '80'	Son Do (b) (4)	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	17 Sep 2020 17:54:03

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11

US3642081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11

US3642081

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:53:21

US3642081

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	Son Do (b) (4)	17 Sep 2020 17:53:21

US3642081

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	Son Do (b) (4)	17 Sep 2020 17:55:42

US3642081

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:14:06

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:55:42

US3642081

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:14:06

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 05:52:17
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'MH updated' (Site from DM).	Son Do (b) (4)	04 Nov 2020 17:04:39
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 05:43:31
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Son Do (b) (4)	17 Sep 2020 17:55:42

US3642081

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:14:06

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:55:42

US3642081

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:14:06

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:55:42

US3642081

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:14:06

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:55:42

US3642081

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:14:06

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:55:42

US3642081

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:14:06

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'I'	Son Do (b) (4)	17 Sep 2020 17:55:42

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

[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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

[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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

[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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'I'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '0'	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:56:07

US3642081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:52:58

US3642081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:52:58

US3642081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:52:58

US3642081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'VISIT1'	System	02 Sep 2020 22:52:58

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:34:37

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '189495'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:34:37

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:34:37

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

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)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:53:10

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

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)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:53:10

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:53:10

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:53:10

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:53:10

US3642081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:06

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Megan Loughran (b) (4)	01 Oct 2020 21:11:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:02:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:02:49

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 10:49:31
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:11:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:11:36
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 21:42:52
User entered '165.0' cm	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:11:36
User entered '62.1' kg	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 10:49:31
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:11:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:11:36
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 21:42:52
User entered '165.0' cm	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:11:36
User entered '62.1' kg	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '13:58'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered '02 Sep 2020 13:58'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '99.8' F	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Oral (Oral)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	24 Nov 2020 20:49:27
User entered 'Axillary (Axillary)'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '87'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'bpm'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '17'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'breaths/min'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '134'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'mmHg'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '80'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'mmHg'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 10:49:31
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:11:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:11:36
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 21:42:52
User entered '165.0' cm	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 21:11:36
User entered '62.1' kg	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '16:22'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered '02 Sep 2020 16:22'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '98.5' F	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) Colleen McLellan (b) (4)	24 Nov 2020 20:49:27
User entered 'Axillary (Axillary)'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '73'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'bpm'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '16'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'breaths/min'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '132'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'mmHg'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '63'	Son Do (b) (4)	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'mmHg'	System	17 Sep 2020 17:54:55

US3642081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)' reason for change: Data Entry Error	Son Do (b) (4)	04 Feb 2021 17:10:56
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:53:30

US3642081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty; reason for change Data Entry Error	(b) (4)	
	Son Do (b) (4)	04 Feb 2021 17:10:56
User entered '02 Sep 2020'	Son Do (b) (4)	17 Sep 2020 17:53:30

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

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)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '15:39'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered '02 Sep 2020 15:39'	System	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'ONCE'	System	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 22:58:34

US3642081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:55:08

US3642081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	Son Do (b) (4)	17 Sep 2020 17:55:08

US3642081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '15:00'	Son Do (b) (4)	17 Sep 2020 17:55:08

US3642081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered '02 Sep 2020 15:00'	System	17 Sep 2020 17:55:08

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:14:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '02 Sep 2020'	Son Do (b) (4)	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '14:55'	Son Do (b) (4)	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered '02 Sep 2020 14:55'	System	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered empty.	System	17 Sep 2020 17:55:21

US3642081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	09 Sep 2020 17:30:58

US3642081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered '1'	System	09 Sep 2020 17:30:58

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:00:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'dd92c5af-e28f-4915-8c23-c7b0340df98e' User entered 'Yes (Y)'	System	02 Sep 2020 23:02:25
	System	02 Sep 2020 23:02:25

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:02:06', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'dd92c5af-e28f-4915-8c23-c7b0340df98e' User entered '97.9'	System	02 Sep 2020 23:02:25
	System	02 Sep 2020 23:02:25

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:02:17', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'dd92c5af-e28f-4915-8c23-c7b0340df98e' User entered 'No (N)'	System	02 Sep 2020 23:02:25
	System	02 Sep 2020 23:02:25

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:02:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'dd92c5af-e28f-4915-8c23-c7b0340df98e' User entered '02 Sep 2020 16:02'	System	02 Sep 2020 23:02:25
	System	02 Sep 2020 23:02:25

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 15:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 18:29'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 19:24'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 2'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:15:54', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5a48ec6e-e2a7-4c0d-a16f-3cc55d70ea93'	System	03 Sep 2020 23:00:19
User entered 'Yes (Y)'	System	03 Sep 2020 23:00:19

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:16:03', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5a48ec6e-e2a7-4c0d-a16f-3cc55d70ea93' User entered '98.2'	System	03 Sep 2020 23:00:19
	System	03 Sep 2020 23:00:19

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T16:00:14', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5a48ec6e-e2a7-4c0d-a16f-3cc55d70ea93'	System	03 Sep 2020 23:00:19
User entered 'No (N)'	System	03 Sep 2020 23:00:19

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T16:00:18', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5a48ec6e-e2a7-4c0d-a16f-3cc55d70ea93'	System	03 Sep 2020 23:00:19
User entered '03 Sep 2020 16:00'	System	03 Sep 2020 23:00:19

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 3'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:08:49', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4293b8d4-bd67-4f82-914b-4048d2139a7a' User entered 'Yes (Y)'	System	04 Sep 2020 22:09:11
	System	04 Sep 2020 22:09:11

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:08:58', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4293b8d4-bd67-4f82-914b-4048d2139a7a' User entered '98.2'	System	04 Sep 2020 22:09:11
	System	04 Sep 2020 22:09:11

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:09:02', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4293b8d4-bd67-4f82-914b-4048d2139a7a'	System	04 Sep 2020 22:09:11
User entered 'No (N)'	System	04 Sep 2020 22:09:11

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:09:08', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4293b8d4-bd67-4f82-914b-4048d2139a7a' User entered '04 Sep 2020 15:09'	System	04 Sep 2020 22:09:11
	System	04 Sep 2020 22:09:11

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 4'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:32:12', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '079712d3-0dd6-4adc-a503-8996587e9edb' User entered 'Yes (Y)'	System	05 Sep 2020 22:32:35
	System	05 Sep 2020 22:32:35

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:32:20', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '079712d3-0dd6-4adc-a503-8996587e9edb' User entered '98.5'	System	05 Sep 2020 22:32:35
	System	05 Sep 2020 22:32:35

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:32:26', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '079712d3-0dd6-4adc-a503-8996587e9edb' User entered 'No (N)'	System	05 Sep 2020 22:32:35
	System	05 Sep 2020 22:32:35

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:32:32', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '079712d3-0dd6-4adc-a503-8996587e9edb' User entered '05 Sep 2020 15:32'	System	05 Sep 2020 22:32:35
	System	05 Sep 2020 22:32:35

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 5'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:11', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e8032773-15f4-4c72-b0ea-4ab0dc554d1c' User entered 'Yes (Y)'	System	06 Sep 2020 21:24:28
	System	06 Sep 2020 21:24:28

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:15', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e8032773-15f4-4c72-b0ea-4ab0dc554d1c' User entered '98.6'	System	06 Sep 2020 21:24:28
	System	06 Sep 2020 21:24:28

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:19', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e8032773-15f4-4c72-b0ea-4ab0dc554d1c' User entered 'No (N)'	System	06 Sep 2020 21:24:28
	System	06 Sep 2020 21:24:28

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:25', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e8032773-15f4-4c72-b0ea-4ab0dc554d1c' User entered '06 Sep 2020 14:24'	System	06 Sep 2020 21:24:28
	System	06 Sep 2020 21:24:28

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 6'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:10:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '50053518-104f-47fd-b7d0-409096058674' User entered 'Yes (Y)'	System	07 Sep 2020 21:10:48
	System	07 Sep 2020 21:10:48

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:10:38', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '50053518-104f-47fd-b7d0-409096058674' User entered '98.3'	System	07 Sep 2020 21:10:48
	System	07 Sep 2020 21:10:48

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:10:41', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '50053518-104f-47fd-b7d0-409096058674' User entered 'No (N)'	System	07 Sep 2020 21:10:48
	System	07 Sep 2020 21:10:48

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:10:45', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '50053518-104f-47fd-b7d0-409096058674' User entered '07 Sep 2020 14:10'	System	07 Sep 2020 21:10:48
	System	07 Sep 2020 21:10:48

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 7'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:21:52', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd5f92ef8-5587-44f8-868c-0e6f79eddc81' User entered 'Yes (Y)'	System	08 Sep 2020 20:22:10
	System	08 Sep 2020 20:22:10

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:21:57', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd5f92ef8-5587-44f8-868c-0e6f79eddc81' User entered '97.3'	System	08 Sep 2020 20:22:10
	System	08 Sep 2020 20:22:10

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:22:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd5f92ef8-5587-44f8-868c-0e6f79eddc81'	System	08 Sep 2020 20:22:10
User entered 'No (N)'	System	08 Sep 2020 20:22:10

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:22:06', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd5f92ef8-5587-44f8-868c-0e6f79eddc81' User entered '08 Sep 2020 13:22'	System	08 Sep 2020 20:22:10
	System	08 Sep 2020 20:22:10

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:02:54', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9b35c8a5-deab-4185-a572-1064ee628c89'	System	02 Sep 2020 23:03:31
User entered 'None (1)'	System	02 Sep 2020 23:03:31

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:10', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9b35c8a5-deab-4185-a572-1064ee628c89' User entered 'No (N)'	System	02 Sep 2020 23:03:31
	System	02 Sep 2020 23:03:31

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:16', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9b35c8a5-deab-4185-a572-1064ee628c89' User entered 'No (N)'	System	02 Sep 2020 23:03:31
	System	02 Sep 2020 23:03:31

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:25', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9b35c8a5-deab-4185-a572-1064ee628c89'	System	02 Sep 2020 23:03:31
User entered 'None (1)'	System	02 Sep 2020 23:03:31

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:29', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9b35c8a5-deab-4185-a572-1064ee628c89' User entered '02 Sep 2020 16:03'	System	02 Sep 2020 23:03:31
	System	02 Sep 2020 23:03:31

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 15:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 18:29'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 19:24'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 2'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:16:31', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4ba84afe-593a-482e-84d2-25f18759fc6d'	System	03 Sep 2020 22:16:53
User entered 'None (1)'	System	03 Sep 2020 22:16:53

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:16:35', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4ba84afe-593a-482e-84d2-25f18759fc6d' User entered 'No (N)'	System	03 Sep 2020 22:16:53
	System	03 Sep 2020 22:16:53

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:16:38', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4ba84afe-593a-482e-84d2-25f18759fc6d' User entered 'No (N)'	System	03 Sep 2020 22:16:53
	System	03 Sep 2020 22:16:53

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:16:46', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4ba84afe-593a-482e-84d2-25f18759fc6d' User entered 'None (1)'	System	03 Sep 2020 22:16:53
	System	03 Sep 2020 22:16:53

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:16:50', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '4ba84afe-593a-482e-84d2-25f18759fc6d' User entered '03 Sep 2020 15:16'	System	03 Sep 2020 22:16:53
	System	03 Sep 2020 22:16:53

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 3'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:09:43', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '6b444913-87b8-4264-9034-0a983f95d401'	System	04 Sep 2020 22:10:13
User entered 'None (1)'	System	04 Sep 2020 22:10:13

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:09:48', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '6b444913-87b8-4264-9034-0a983f95d401' User entered 'No (N)'	System	04 Sep 2020 22:10:13
	System	04 Sep 2020 22:10:13

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:09:51', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '6b444913-87b8-4264-9034-0a983f95d401' User entered 'No (N)'	System	04 Sep 2020 22:10:13
	System	04 Sep 2020 22:10:13

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:01', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '6b444913-87b8-4264-9034-0a983f95d401'	System	04 Sep 2020 22:10:13
User entered 'None (1)'	System	04 Sep 2020 22:10:13

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:06', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '6b444913-87b8-4264-9034-0a983f95d401' User entered '04 Sep 2020 15:10'	System	04 Sep 2020 22:10:13
	System	04 Sep 2020 22:10:13

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 4'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:32:37', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c6420dd1-0898-49f5-85bd-90504fd394df'	System	05 Sep 2020 22:33:20
User entered 'None (1)'	System	05 Sep 2020 22:33:20

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:32:58', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c6420dd1-0898-49f5-85bd-90504fd394df' User entered 'No (N)'	System	05 Sep 2020 22:33:20
	System	05 Sep 2020 22:33:20

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:04', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c6420dd1-0898-49f5-85bd-90504fd394df' User entered 'No (N)'	System	05 Sep 2020 22:33:20
	System	05 Sep 2020 22:33:20

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:12', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c6420dd1-0898-49f5-85bd-90504fd394df' User entered 'None (1)'	System	05 Sep 2020 22:33:20
	System	05 Sep 2020 22:33:20

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:19', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c6420dd1-0898-49f5-85bd-90504fd394df' User entered '05 Sep 2020 15:33'	System	05 Sep 2020 22:33:20
	System	05 Sep 2020 22:33:20

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 5'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:23:27', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd82f5457-33d5-413b-9f13-6973cd14a28f' User entered 'None (1)'	System	06 Sep 2020 21:23:59
	System	06 Sep 2020 21:23:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:23:30', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd82f5457-33d5-413b-9f13-6973cd14a28f' User entered 'No (N)'	System	06 Sep 2020 21:23:59
	System	06 Sep 2020 21:23:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:23:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd82f5457-33d5-413b-9f13-6973cd14a28f' User entered 'No (N)'	System	06 Sep 2020 21:23:59
	System	06 Sep 2020 21:23:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:23:49', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd82f5457-33d5-413b-9f13-6973cd14a28f' User entered 'None (1)'	System	06 Sep 2020 21:23:59
	System	06 Sep 2020 21:23:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:23:53', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd82f5457-33d5-413b-9f13-6973cd14a28f' User entered '06 Sep 2020 14:23'	System	06 Sep 2020 21:23:59
	System	06 Sep 2020 21:23:59

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 6'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:10:48', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '62042d12-821e-44f3-83d9-0795377d2d74'	System	07 Sep 2020 21:11:01
User entered 'None (1)'	System	07 Sep 2020 21:11:01

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:10:51', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '62042d12-821e-44f3-83d9-0795377d2d74'	System	07 Sep 2020 21:11:01
User entered 'No (N)'	System	07 Sep 2020 21:11:01

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:10:54', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '62042d12-821e-44f3-83d9-0795377d2d74' User entered 'No (N)'	System	07 Sep 2020 21:11:01
	System	07 Sep 2020 21:11:01

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:10:57', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '62042d12-821e-44f3-83d9-0795377d2d74'	System	07 Sep 2020 21:11:01
User entered 'None (1)'	System	07 Sep 2020 21:11:01

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '62042d12-821e-44f3-83d9-0795377d2d74' User entered '07 Sep 2020 14:11'	System	07 Sep 2020 21:11:01
	System	07 Sep 2020 21:11:01

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 7'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:22:16', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '3d66cc88-dc6f-4073-b00e-dfc8488f1e97'	System	08 Sep 2020 20:22:39
User entered 'None (1)'	System	08 Sep 2020 20:22:39

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:22:22', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '3d66cc88-dc6f-4073-b00e-dfc8488f1e97'	System	08 Sep 2020 20:22:39
User entered 'No (N)'	System	08 Sep 2020 20:22:39

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:22:26', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '3d66cc88-dc6f-4073-b00e-dfc8488f1e97'	System	08 Sep 2020 20:22:39
User entered 'No (N)'	System	08 Sep 2020 20:22:39

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:22:32', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '3d66cc88-dc6f-4073-b00e-dfc8488f1e97'	System	08 Sep 2020 20:22:39
User entered 'None (1)'	System	08 Sep 2020 20:22:39

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:22:37', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '3d66cc88-dc6f-4073-b00e-dfc8488f1e97' User entered '08 Sep 2020 13:22'	System	08 Sep 2020 20:22:39
	System	08 Sep 2020 20:22:39

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:37', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '17c643ab-f18f-4e98-86c0-4a0f888e3103' User entered 'None (0)'	System	02 Sep 2020 23:04:08
	System	02 Sep 2020 23:04:08

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:41', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '17c643ab-f18f-4e98-86c0-4a0f888e3103' User entered 'None (0)'	System	02 Sep 2020 23:04:08
	System	02 Sep 2020 23:04:08

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:43', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '17c643ab-f18f-4e98-86c0-4a0f888e3103' User entered 'None (0)'	System	02 Sep 2020 23:04:08
	System	02 Sep 2020 23:04:08

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:46', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '17c643ab-f18f-4e98-86c0-4a0f888e3103' User entered 'None (0)'	System	02 Sep 2020 23:04:08
	System	02 Sep 2020 23:04:08

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:49', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '17c643ab-f18f-4e98-86c0-4a0f888e3103' User entered 'None (0)'	System	02 Sep 2020 23:04:08
	System	02 Sep 2020 23:04:08

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:52', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '17c643ab-f18f-4e98-86c0-4a0f888e3103' User entered 'None (0)'	System	02 Sep 2020 23:04:08
	System	02 Sep 2020 23:04:08

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:03:58', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '17c643ab-f18f-4e98-86c0-4a0f888e3103'	System	02 Sep 2020 23:04:08
User entered 'No (N)'	System	02 Sep 2020 23:04:08

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-02T16:04:04', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '17c643ab-f18f-4e98-86c0-4a0f888e3103' User entered '02 Sep 2020 16:04'	System	02 Sep 2020 23:04:08
	System	02 Sep 2020 23:04:08

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 15:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 18:29'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Sep 2020 19:24'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 2'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:16:57', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '99a6a0ab-9863-4de9-99d4-0f2c207bd99e' User entered 'None (0)'	System	03 Sep 2020 22:17:26
	System	03 Sep 2020 22:17:26

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:17:01', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '99a6a0ab-9863-4de9-99d4-0f2c207bd99e' User entered 'None (0)'	System	03 Sep 2020 22:17:26
	System	03 Sep 2020 22:17:26

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:17:03', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '99a6a0ab-9863-4de9-99d4-0f2c207bd99e' User entered 'None (0)'	System	03 Sep 2020 22:17:26
	System	03 Sep 2020 22:17:26

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:17:06', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '99a6a0ab-9863-4de9-99d4-0f2c207bd99e' User entered 'None (0)'	System	03 Sep 2020 22:17:26
	System	03 Sep 2020 22:17:26

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:17:09', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '99a6a0ab-9863-4de9-99d4-0f2c207bd99e' User entered 'None (0)'	System	03 Sep 2020 22:17:26
	System	03 Sep 2020 22:17:26

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:17:11', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '99a6a0ab-9863-4de9-99d4-0f2c207bd99e' User entered 'None (0)'	System	03 Sep 2020 22:17:26
	System	03 Sep 2020 22:17:26

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:17:17', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '99a6a0ab-9863-4de9-99d4-0f2c207bd99e' User entered 'No (N)'	System	03 Sep 2020 22:17:26
	System	03 Sep 2020 22:17:26

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-03T15:17:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '99a6a0ab-9863-4de9-99d4-0f2c207bd99e' User entered '03 Sep 2020 15:17'	System	03 Sep 2020 22:17:26
	System	03 Sep 2020 22:17:26

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 3'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:11', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5314e2e9-b284-478a-9953-757951ed4c5d' User entered 'None (0)'	System	04 Sep 2020 22:10:39
	System	04 Sep 2020 22:10:39

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:13', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5314e2e9-b284-478a-9953-757951ed4c5d' User entered 'None (0)'	System	04 Sep 2020 22:10:39
	System	04 Sep 2020 22:10:39

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:16', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5314e2e9-b284-478a-9953-757951ed4c5d' User entered 'None (0)'	System	04 Sep 2020 22:10:39
	System	04 Sep 2020 22:10:39

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:19', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5314e2e9-b284-478a-9953-757951ed4c5d' User entered 'None (0)'	System	04 Sep 2020 22:10:39
	System	04 Sep 2020 22:10:39

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:21', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5314e2e9-b284-478a-9953-757951ed4c5d' User entered 'None (0)'	System	04 Sep 2020 22:10:39
	System	04 Sep 2020 22:10:39

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5314e2e9-b284-478a-9953-757951ed4c5d' User entered 'None (0)'	System	04 Sep 2020 22:10:39
	System	04 Sep 2020 22:10:39

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:29', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5314e2e9-b284-478a-9953-757951ed4c5d' User entered 'No (N)'	System	04 Sep 2020 22:10:39
	System	04 Sep 2020 22:10:39

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-04T15:10:35', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5314e2e9-b284-478a-9953-757951ed4c5d' User entered '04 Sep 2020 15:10'	System	04 Sep 2020 22:10:39
	System	04 Sep 2020 22:10:39

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 4'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a5243669-847e-42a2-a4b4-bd42e37effc9' User entered 'None (0)'	System	05 Sep 2020 22:33:45
	System	05 Sep 2020 22:33:45

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:27', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a5243669-847e-42a2-a4b4-bd42e37effc9' User entered 'None (0)'	System	05 Sep 2020 22:33:45
	System	05 Sep 2020 22:33:45

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:29', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a5243669-847e-42a2-a4b4-bd42e37effc9' User entered 'None (0)'	System	05 Sep 2020 22:33:45
	System	05 Sep 2020 22:33:45

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:31', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a5243669-847e-42a2-a4b4-bd42e37effc9' User entered 'None (0)'	System	05 Sep 2020 22:33:45
	System	05 Sep 2020 22:33:45

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a5243669-847e-42a2-a4b4-bd42e37effc9' User entered 'None (0)'	System	05 Sep 2020 22:33:45
	System	05 Sep 2020 22:33:45

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:35', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a5243669-847e-42a2-a4b4-bd42e37effc9' User entered 'None (0)'	System	05 Sep 2020 22:33:45
	System	05 Sep 2020 22:33:45

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:38', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a5243669-847e-42a2-a4b4-bd42e37effc9' User entered 'No (N)'	System	05 Sep 2020 22:33:45
	System	05 Sep 2020 22:33:45

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-05T15:33:44', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a5243669-847e-42a2-a4b4-bd42e37effc9' User entered '05 Sep 2020 15:33'	System	05 Sep 2020 22:33:45
	System	05 Sep 2020 22:33:45

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 5'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:29', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0af89f4c-66e0-4a0a-95b9-9a2e12ed1def' User entered 'None (0)'	System	06 Sep 2020 21:25:00
	System	06 Sep 2020 21:25:00

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0af89f4c-66e0-4a0a-95b9-9a2e12ed1def' User entered 'None (0)'	System	06 Sep 2020 21:25:00
	System	06 Sep 2020 21:25:00

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:36', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0af89f4c-66e0-4a0a-95b9-9a2e12ed1def' User entered 'None (0)'	System	06 Sep 2020 21:25:00
	System	06 Sep 2020 21:25:00

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:40', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0af89f4c-66e0-4a0a-95b9-9a2e12ed1def' User entered 'None (0)'	System	06 Sep 2020 21:25:00
	System	06 Sep 2020 21:25:00

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:43', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0af89f4c-66e0-4a0a-95b9-9a2e12ed1def' User entered 'None (0)'	System	06 Sep 2020 21:25:00
	System	06 Sep 2020 21:25:00

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:46', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0af89f4c-66e0-4a0a-95b9-9a2e12ed1def' User entered 'None (0)'	System	06 Sep 2020 21:25:00
	System	06 Sep 2020 21:25:00

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:51', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0af89f4c-66e0-4a0a-95b9-9a2e12ed1def' User entered 'No (N)'	System	06 Sep 2020 21:25:00
	System	06 Sep 2020 21:25:00

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-06T14:24:57', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0af89f4c-66e0-4a0a-95b9-9a2e12ed1def' User entered '06 Sep 2020 14:24'	System	06 Sep 2020 21:25:00
	System	06 Sep 2020 21:25:00

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 6'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:05', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '21c28745-3e39-45e7-a2ce-745ebeb37ea6' User entered 'None (0)'	System	07 Sep 2020 21:11:28
	System	07 Sep 2020 21:11:28

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:07', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '21c28745-3e39-45e7-a2ce-745ebeb37ea6' User entered 'None (0)'	System	07 Sep 2020 21:11:28
	System	07 Sep 2020 21:11:28

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:09', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '21c28745-3e39-45e7-a2ce-745ebeb37ea6' User entered 'None (0)'	System	07 Sep 2020 21:11:28
	System	07 Sep 2020 21:11:28

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:11', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '21c28745-3e39-45e7-a2ce-745ebeb37ea6' User entered 'None (0)'	System	07 Sep 2020 21:11:28
	System	07 Sep 2020 21:11:28

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:13', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '21c28745-3e39-45e7-a2ce-745ebeb37ea6' User entered 'None (0)'	System	07 Sep 2020 21:11:28
	System	07 Sep 2020 21:11:28

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:15', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '21c28745-3e39-45e7-a2ce-745ebeb37ea6' User entered 'None (0)'	System	07 Sep 2020 21:11:28
	System	07 Sep 2020 21:11:28

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:21', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '21c28745-3e39-45e7-a2ce-745ebeb37ea6' User entered 'No (N)'	System	07 Sep 2020 21:11:28
	System	07 Sep 2020 21:11:28

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-07T14:11:26', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '21c28745-3e39-45e7-a2ce-745ebeb37ea6' User entered '07 Sep 2020 14:11'	System	07 Sep 2020 21:11:28
	System	07 Sep 2020 21:11:28

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 7'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:22:42', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9a4fa5eb-f908-4911-b843-8d623fbbb434' User entered 'None (0)'	System	08 Sep 2020 20:23:33
	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:23:03', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9a4fa5eb-f908-4911-b843-8d623fbbb434'	System	08 Sep 2020 20:23:33
User entered 'No interference with activity (1)'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:23:06', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9a4fa5eb-f908-4911-b843-8d623fbbb434' User entered 'None (0)'	System	08 Sep 2020 20:23:33
	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:23:08', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9a4fa5eb-f908-4911-b843-8d623fbbb434' User entered 'None (0)'	System	08 Sep 2020 20:23:33
	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:23:12', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9a4fa5eb-f908-4911-b843-8d623fbbb434' User entered 'None (0)'	System	08 Sep 2020 20:23:33
	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:23:14', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9a4fa5eb-f908-4911-b843-8d623fbbb434' User entered 'None (0)'	System	08 Sep 2020 20:23:33
	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:23:20', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9a4fa5eb-f908-4911-b843-8d623fbbb434' User entered 'No (N)'	System	08 Sep 2020 20:23:33
	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-09-08T13:23:29', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9a4fa5eb-f908-4911-b843-8d623fbbb434' User entered '08 Sep 2020 13:23'	System	08 Sep 2020 20:23:33
	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	08 Sep 2020 20:23:33
User entered 'Day 8'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	08 Sep 2020 20:23:33
User entered 'Day 9'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	08 Sep 2020 20:23:33
User entered 'Day 8'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	08 Sep 2020 20:23:33
User entered 'Day 9'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:23:33

US3642081

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:23:33

US3642081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	10 Sep 2020 00:54:04

US3642081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '9 Sep 2020'	Colleen McLellan (b) (4)	10 Sep 2020 00:54:04

US3642081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colleen McLellan (b) (4)	10 Sep 2020 00:54:04

US3642081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Colleen McLellan (b) (4)	10 Sep 2020 00:54:04

US3642081

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	10 Sep 2020 00:53:55

US3642081

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'I'	System	10 Sep 2020 00:53:55

US3642081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:40:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:40:54
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Sep 2020 21:40:54
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 16:07:32
User entered empty.	Colleen McLellan (b) (4)	17 Sep 2020 16:07:32
	(b) (4)	

US3642081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '18 Sep 2020' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:40:54
User entered empty.	Colleen McLellan (b) (4) (b) (4)	17 Sep 2020 16:07:32

US3642081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Contact Made (CONTACT MADE)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:40:54
User entered empty.	Colleen McLellan (b) (4) (b) (4)	17 Sep 2020 16:07:32

US3642081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Colleen McLellan (b) (4)	17 Sep 2020 16:07:32

US3642081

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:05

US3642081

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:42:54
User entered 'I'	System	18 Sep 2020 21:41:05

US3642081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	29 Mar 2021 22:04:05

US3642081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered '23 Sep 2020'	(b) (4) Colleen McLellan (b) (4)	29 Mar 2021 22:04:05

US3642081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colleen McLellan (b) (4)	29 Mar 2021 22:04:05

US3642081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	Colleen McLellan (b) (4)	29 Mar 2021 22:04:05

US3642081

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 22:09:39

US3642081

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User entered 'I'	System	01 Oct 2020 22:09:39

US3642081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 22:09:49

US3642081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '1 Oct 2020'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 22:09:49

US3642081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4)	01 Oct 2020 22:09:49

US3642081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'VISIT2'	System	01 Oct 2020 22:09:49

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '14:47'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered '01 Oct 2020 14:47'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '98.7' F	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Oral (Oral)'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '85'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'bpm'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '16'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'breaths/min'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '117'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'mmHg'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '75'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'mmHg'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '16:55'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered '01 Oct 2020 16:55'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '98.6' F	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Oral (Oral)'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '81'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'bpm'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '15'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'breaths/min'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '117'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'mmHg'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 08:52:55
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Colleen McLellan (b) (4) (b) (4)	24 Nov 2020 20:48:46
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Oct 2020 16:26:02
User entered '55'	Son Do (b) (4)	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'mmHg'	System	05 Oct 2020 16:26:02

US3642081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:26:32

US3642081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:26:32

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

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)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Megan Loughran (b) (4)	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '1 Oct 2020'	Megan Loughran (b) (4)	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '16:25'	(b) (4) Megan Loughran (b) (4)	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered '1 Oct 2020 16:25'	System	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Left Arm (LEFT ARM)'	Megan Loughran (b) (4)	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'ONCE'	System	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 23:29:14

US3642081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:26:43

US3642081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:26:43

US3642081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '16:04'	Son Do (b) (4)	05 Oct 2020 16:26:43

US3642081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered '01 Oct 2020 16:04'	System	05 Oct 2020 16:26:43

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:14:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '16:06'	Son Do (b) (4)	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered '01 Oct 2020 16:06'	System	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)'	Son Do (b) (4)	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered empty.	System	05 Oct 2020 16:26:55

US3642081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:27:00

US3642081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered '1'	System	05 Oct 2020 16:27:00

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:46:14', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd92c3d9d-a7c1-49c4-b24a-5493916c091a' User entered 'Yes (Y)'	System	01 Oct 2020 23:46:38
	System	01 Oct 2020 23:46:38

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:46:21', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd92c3d9d-a7c1-49c4-b24a-5493916c091a' User entered '98.6'	System	01 Oct 2020 23:46:38
	System	01 Oct 2020 23:46:38

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:46:27', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd92c3d9d-a7c1-49c4-b24a-5493916c091a' User entered 'No (N)'	System	01 Oct 2020 23:46:38
	System	01 Oct 2020 23:46:38

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:46:35', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd92c3d9d-a7c1-49c4-b24a-5493916c091a' User entered '01 Oct 2020 16:46'	System	01 Oct 2020 23:46:38
	System	01 Oct 2020 23:46:38

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 16:45'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 19:15'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:17:25', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '46720b1e-e880-42ca-8cc4-ed43733298eb' User entered 'Yes (Y)'	System	02 Oct 2020 04:17:45
	System	02 Oct 2020 04:17:45

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:17:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '46720b1e-e880-42ca-8cc4-ed43733298eb' User entered '97.6'	System	02 Oct 2020 04:17:45
	System	02 Oct 2020 04:17:45

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:17:37', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '46720b1e-e880-42ca-8cc4-ed43733298eb' User entered 'No (N)'	System	02 Oct 2020 04:17:45
	System	02 Oct 2020 04:17:45

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:17:43', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '46720b1e-e880-42ca-8cc4-ed43733298eb' User entered '01 Oct 2020 21:17'	System	02 Oct 2020 04:17:45
	System	02 Oct 2020 04:17:45

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 20:10'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 2'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:05:40', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '2cef696b-0aa6-4882-9f33-ce4a6568675d' User entered 'Yes (Y)'	System	02 Oct 2020 23:06:00
	System	02 Oct 2020 23:06:00

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:05:45', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '2cef696b-0aa6-4882-9f33-ce4a6568675d' User entered '98.7'	System	02 Oct 2020 23:06:00
	System	02 Oct 2020 23:06:00

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:05:50', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '2cef696b-0aa6-4882-9f33-ce4a6568675d' User entered 'No (N)'	System	02 Oct 2020 23:06:00
	System	02 Oct 2020 23:06:00

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:05:55', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '2cef696b-0aa6-4882-9f33-ce4a6568675d' User entered '02 Oct 2020 16:05'	System	02 Oct 2020 23:06:00
	System	02 Oct 2020 23:06:00

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 3'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:22:04', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '340fd73f-45b5-4a85-88db-d1867cb0c7d8' User entered 'Yes (Y)'	System	03 Oct 2020 23:23:27
	System	03 Oct 2020 23:23:27

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:23:17', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '340fd73f-45b5-4a85-88db-d1867cb0c7d8' User entered '98.7'	System	03 Oct 2020 23:23:27
	System	03 Oct 2020 23:23:27

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:23:20', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '340fd73f-45b5-4a85-88db-d1867cb0c7d8'	System	03 Oct 2020 23:23:27
User entered 'No (N)'	System	03 Oct 2020 23:23:27

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:23:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '340fd73f-45b5-4a85-88db-d1867cb0c7d8' User entered '03 Oct 2020 16:23'	System	03 Oct 2020 23:23:27
	System	03 Oct 2020 23:23:27

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 4'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:32:34', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1239468f-53fe-48e4-974a-2447af7fa604' User entered 'Yes (Y)'	System	05 Oct 2020 09:33:12
	System	05 Oct 2020 09:33:12

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:32:43', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1239468f-53fe-48e4-974a-2447af7fa604' User entered '98.3'	System	05 Oct 2020 09:33:12
	System	05 Oct 2020 09:33:12

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:32:53', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1239468f-53fe-48e4-974a-2447af7fa604'	System	05 Oct 2020 09:33:12
User entered 'Yes (Y)'	System	05 Oct 2020 09:33:12

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PARTICIPANT WAS CONTACTED BY STUDY STAFF - SEE SAFETY CALL SOURCE DOC FOR ADDITIONAL INFO ' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 04:57:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Colleen McLellan (b) (4)	20 Nov 2020 05:42:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:04', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1239468f-53fe-48e4-974a-2447af7fa604'	System	05 Oct 2020 09:33:12
User entered '1'	System	05 Oct 2020 09:33:12

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:04', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1239468f-53fe-48e4-974a-2447af7fa604' User entered '0'	System	05 Oct 2020 09:33:12
	System	05 Oct 2020 09:33:12

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:11', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1239468f-53fe-48e4-974a-2447af7fa604' User entered '05 Oct 2020 02:33'	System	05 Oct 2020 09:33:12
	System	05 Oct 2020 09:33:12

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 5'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:05', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f71845c3-6e95-4b82-9e85-d69e5cd5cfdd' User entered 'Yes (Y)'	System	05 Oct 2020 22:24:20
	System	05 Oct 2020 22:24:20

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:10', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f71845c3-6e95-4b82-9e85-d69e5cd5cfdd' User entered '98.2'	System	05 Oct 2020 22:24:20
	System	05 Oct 2020 22:24:20

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:13', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f71845c3-6e95-4b82-9e85-d69e5cd5cfdd'	System	05 Oct 2020 22:24:20
User entered 'No (N)'	System	05 Oct 2020 22:24:20

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:17', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f71845c3-6e95-4b82-9e85-d69e5cd5cfdd' User entered '05 Oct 2020 15:24'	System	05 Oct 2020 22:24:20
	System	05 Oct 2020 22:24:20

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 6'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:44:10', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c5014cbb-449c-49ad-9690-81b14bdb301b' User entered 'Yes (Y)'	System	07 Oct 2020 01:45:02
	System	07 Oct 2020 01:45:02

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:44:32', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c5014cbb-449c-49ad-9690-81b14bdb301b' User entered '98.6'	System	07 Oct 2020 01:45:02
	System	07 Oct 2020 01:45:02

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:44:50', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c5014cbb-449c-49ad-9690-81b14bdb301b' User entered 'Yes (Y)'	System	07 Oct 2020 01:45:02
	System	07 Oct 2020 01:45:02

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PARTICIPANT WAS CONTACTED BY STUDY STAFF - SEE SAFETY CALL SOURCE DOC FOR ADDITIONAL INFO ' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 04:57:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Colleen McLellan (b) (4)	20 Nov 2020 05:42:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:44:54', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c5014cbb-449c-49ad-9690-81b14bdb301b'	System	07 Oct 2020 01:45:02
User entered '1'	System	07 Oct 2020 01:45:02

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:44:54', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c5014cbb-449c-49ad-9690-81b14bdb301b' User entered '0'	System	07 Oct 2020 01:45:02
	System	07 Oct 2020 01:45:02

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:44:59', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c5014cbb-449c-49ad-9690-81b14bdb301b' User entered '06 Oct 2020 18:44'	System	07 Oct 2020 01:45:02
	System	07 Oct 2020 01:45:02

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 7'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:07', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e3993dd8-0fe7-4026-ac4d-0fe8d74eea25' User entered 'Yes (Y)'	System	08 Oct 2020 16:40:21
	System	08 Oct 2020 16:40:21

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:12', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e3993dd8-0fe7-4026-ac4d-0fe8d74eea25' User entered '98.7'	System	08 Oct 2020 16:40:21
	System	08 Oct 2020 16:40:21

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:15', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e3993dd8-0fe7-4026-ac4d-0fe8d74eea25'	System	08 Oct 2020 16:40:21
User entered 'No (N)'	System	08 Oct 2020 16:40:21

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:18', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e3993dd8-0fe7-4026-ac4d-0fe8d74eea25' User entered '08 Oct 2020 09:40'	System	08 Oct 2020 16:40:21
	System	08 Oct 2020 16:40:21

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:13', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a38bbf64-f2e4-406e-9c9b-95c626d8217a' User entered 'None (1)'	System	01 Oct 2020 23:47:30
	System	01 Oct 2020 23:47:30

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:17', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a38bbf64-f2e4-406e-9c9b-95c626d8217a' User entered 'No (N)'	System	01 Oct 2020 23:47:30
	System	01 Oct 2020 23:47:30

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:20', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a38bbf64-f2e4-406e-9c9b-95c626d8217a' User entered 'No (N)'	System	01 Oct 2020 23:47:30
	System	01 Oct 2020 23:47:30

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a38bbf64-f2e4-406e-9c9b-95c626d8217a' User entered 'None (1)'	System	01 Oct 2020 23:47:30
	System	01 Oct 2020 23:47:30

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:27', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a38bbf64-f2e4-406e-9c9b-95c626d8217a' User entered '01 Oct 2020 16:47'	System	01 Oct 2020 23:47:30
	System	01 Oct 2020 23:47:30

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 16:45'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 19:15'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:17:50', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5eadf082-1217-4202-8ffe-a3f452307efa' User entered 'None (1)'	System	02 Oct 2020 04:18:43
	System	02 Oct 2020 04:18:43

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:20', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5eadf082-1217-4202-8ffe-a3f452307efa' User entered 'No (N)'	System	02 Oct 2020 04:18:43
	System	02 Oct 2020 04:18:43

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:26', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5eadf082-1217-4202-8ffe-a3f452307efa' User entered 'No (N)'	System	02 Oct 2020 04:18:43
	System	02 Oct 2020 04:18:43

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:34', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5eadf082-1217-4202-8ffe-a3f452307efa'	System	02 Oct 2020 04:18:43
User entered 'None (1)'	System	02 Oct 2020 04:18:43

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:38', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5eadf082-1217-4202-8ffe-a3f452307efa' User entered '01 Oct 2020 21:18'	System	02 Oct 2020 04:18:43
	System	02 Oct 2020 04:18:43

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 20:10'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 2'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:10', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '208101c8-f25d-4831-8856-7f794689024b' User entered 'None (1)'	System	02 Oct 2020 23:06:33
	System	02 Oct 2020 23:06:33

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:13', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '208101c8-f25d-4831-8856-7f794689024b' User entered 'No (N)'	System	02 Oct 2020 23:06:33
	System	02 Oct 2020 23:06:33

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:18', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '208101c8-f25d-4831-8856-7f794689024b' User entered 'No (N)'	System	02 Oct 2020 23:06:33
	System	02 Oct 2020 23:06:33

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '208101c8-f25d-4831-8856-7f794689024b' User entered 'None (1)'	System	02 Oct 2020 23:06:33
	System	02 Oct 2020 23:06:33

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:28', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '208101c8-f25d-4831-8856-7f794689024b' User entered '02 Oct 2020 16:06'	System	02 Oct 2020 23:06:33
	System	02 Oct 2020 23:06:33

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 3'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:23:43', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'b4214f48-6aa4-4dff-9371-5bfff451b122'	System	03 Oct 2020 23:24:02
User entered 'None (1)'	System	03 Oct 2020 23:24:02

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:23:46', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'b4214f48-6aa4-4dff-9371-5bfff451b122'	System	03 Oct 2020 23:24:02
User entered 'No (N)'	System	03 Oct 2020 23:24:02

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:23:50', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'b4214f48-6aa4-4dff-9371-5bfff451b122'	System	03 Oct 2020 23:24:02
User entered 'No (N)'	System	03 Oct 2020 23:24:02

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:23:56', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'b4214f48-6aa4-4dff-9371-5bfff451b122'	System	03 Oct 2020 23:24:02
User entered 'None (1)'	System	03 Oct 2020 23:24:02

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:23:59', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'b4214f48-6aa4-4dff-9371-5bfff451b122'	System	03 Oct 2020 23:24:02
User entered '03 Oct 2020 16:23'	System	03 Oct 2020 23:24:02

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 4'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:20', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e7c95457-ae72-4402-bcf1-29bafc8bda4f' User entered 'None (1)'	System	05 Oct 2020 09:33:37
	System	05 Oct 2020 09:33:37

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:23', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e7c95457-ae72-4402-bcf1-29bafc8bda4f' User entered 'No (N)'	System	05 Oct 2020 09:33:37
	System	05 Oct 2020 09:33:37

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:27', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e7c95457-ae72-4402-bcf1-29bafc8bda4f' User entered 'No (N)'	System	05 Oct 2020 09:33:37
	System	05 Oct 2020 09:33:37

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:30', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e7c95457-ae72-4402-bcf1-29bafc8bda4f' User entered 'None (1)'	System	05 Oct 2020 09:33:37
	System	05 Oct 2020 09:33:37

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:34', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e7c95457-ae72-4402-bcf1-29bafc8bda4f' User entered '05 Oct 2020 02:33'	System	05 Oct 2020 09:33:37
	System	05 Oct 2020 09:33:37

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 5'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '670850f3-b116-45ee-b5ac-209327444590' User entered 'None (1)'	System	05 Oct 2020 22:24:50
	System	05 Oct 2020 22:24:50

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:35', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '670850f3-b116-45ee-b5ac-209327444590' User entered 'No (N)'	System	05 Oct 2020 22:24:50
	System	05 Oct 2020 22:24:50

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:40', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '670850f3-b116-45ee-b5ac-209327444590' User entered 'No (N)'	System	05 Oct 2020 22:24:50
	System	05 Oct 2020 22:24:50

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:45', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '670850f3-b116-45ee-b5ac-209327444590' User entered 'None (1)'	System	05 Oct 2020 22:24:50
	System	05 Oct 2020 22:24:50

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:48', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '670850f3-b116-45ee-b5ac-209327444590' User entered '05 Oct 2020 15:24'	System	05 Oct 2020 22:24:50
	System	05 Oct 2020 22:24:50

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 6'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:03', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0fe0c3b9-0b59-4110-acb3-54d3c7853967' User entered 'None (1)'	System	07 Oct 2020 01:45:21
	System	07 Oct 2020 01:45:21

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:09', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0fe0c3b9-0b59-4110-acb3-54d3c7853967'	System	07 Oct 2020 01:45:21
User entered 'No (N)'	System	07 Oct 2020 01:45:21

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:11', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0fe0c3b9-0b59-4110-acb3-54d3c7853967' User entered 'No (N)'	System	07 Oct 2020 01:45:21
	System	07 Oct 2020 01:45:21

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:14', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0fe0c3b9-0b59-4110-acb3-54d3c7853967'	System	07 Oct 2020 01:45:21
User entered 'None (1)'	System	07 Oct 2020 01:45:21

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:18', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0fe0c3b9-0b59-4110-acb3-54d3c7853967' User entered '06 Oct 2020 18:45'	System	07 Oct 2020 01:45:21
	System	07 Oct 2020 01:45:21

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 7'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:23', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '22cb4287-30e6-4143-aed5-ffc36380d9de' User entered 'None (1)'	System	08 Oct 2020 16:40:35
	System	08 Oct 2020 16:40:35

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:26', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '22cb4287-30e6-4143-aed5-ffc36380d9de' User entered 'No (N)'	System	08 Oct 2020 16:40:35
	System	08 Oct 2020 16:40:35

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:28', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '22cb4287-30e6-4143-aed5-ffc36380d9de' User entered 'No (N)'	System	08 Oct 2020 16:40:35
	System	08 Oct 2020 16:40:35

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:30', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '22cb4287-30e6-4143-aed5-ffc36380d9de' User entered 'None (1)'	System	08 Oct 2020 16:40:35
	System	08 Oct 2020 16:40:35

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '22cb4287-30e6-4143-aed5-ffc36380d9de' User entered '08 Oct 2020 09:40'	System	08 Oct 2020 16:40:35
	System	08 Oct 2020 16:40:35

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:35', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f8c5a9d9-bad6-43a4-a949-1e7012cb7a26' User entered 'None (0)'	System	01 Oct 2020 23:48:05
	System	01 Oct 2020 23:48:05

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:37', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f8c5a9d9-bad6-43a4-a949-1e7012cb7a26' User entered 'None (0)'	System	01 Oct 2020 23:48:05
	System	01 Oct 2020 23:48:05

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:40', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f8c5a9d9-bad6-43a4-a949-1e7012cb7a26' User entered 'None (0)'	System	01 Oct 2020 23:48:05
	System	01 Oct 2020 23:48:05

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:43', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f8c5a9d9-bad6-43a4-a949-1e7012cb7a26' User entered 'None (0)'	System	01 Oct 2020 23:48:05
	System	01 Oct 2020 23:48:05

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:45', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f8c5a9d9-bad6-43a4-a949-1e7012cb7a26' User entered 'None (0)'	System	01 Oct 2020 23:48:05
	System	01 Oct 2020 23:48:05

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:48', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f8c5a9d9-bad6-43a4-a949-1e7012cb7a26' User entered 'None (0)'	System	01 Oct 2020 23:48:05
	System	01 Oct 2020 23:48:05

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:47:56', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f8c5a9d9-bad6-43a4-a949-1e7012cb7a26' User entered 'No (N)'	System	01 Oct 2020 23:48:05
	System	01 Oct 2020 23:48:05

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T16:48:01', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f8c5a9d9-bad6-43a4-a949-1e7012cb7a26' User entered '01 Oct 2020 16:48'	System	01 Oct 2020 23:48:05
	System	01 Oct 2020 23:48:05

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 16:45'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 19:15'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:42', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '805e025f-1a28-4d12-bbc3-7ffba357df6c' User entered 'None (0)'	System	02 Oct 2020 04:19:13
	System	02 Oct 2020 04:19:13

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:45', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '805e025f-1a28-4d12-bbc3-7ffba357df6c' User entered 'None (0)'	System	02 Oct 2020 04:19:13
	System	02 Oct 2020 04:19:13

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:49', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '805e025f-1a28-4d12-bbc3-7ffba357df6c' User entered 'None (0)'	System	02 Oct 2020 04:19:13
	System	02 Oct 2020 04:19:13

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:52', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '805e025f-1a28-4d12-bbc3-7ffba357df6c' User entered 'None (0)'	System	02 Oct 2020 04:19:13
	System	02 Oct 2020 04:19:13

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:54', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '805e025f-1a28-4d12-bbc3-7ffba357df6c' User entered 'None (0)'	System	02 Oct 2020 04:19:13
	System	02 Oct 2020 04:19:13

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:18:57', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '805e025f-1a28-4d12-bbc3-7ffba357df6c' User entered 'None (0)'	System	02 Oct 2020 04:19:13
	System	02 Oct 2020 04:19:13

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:19:05', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '805e025f-1a28-4d12-bbc3-7ffba357df6c' User entered 'No (N)'	System	02 Oct 2020 04:19:13
	System	02 Oct 2020 04:19:13

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-01T21:19:10', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '805e025f-1a28-4d12-bbc3-7ffba357df6c' User entered '01 Oct 2020 21:19'	System	02 Oct 2020 04:19:13
	System	02 Oct 2020 04:19:13

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '01 Oct 2020 20:10'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 2'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c403418e-35cf-42ec-9060-c1f2e4d5997b' User entered 'None (0)'	System	02 Oct 2020 23:06:57
	System	02 Oct 2020 23:06:57

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:36', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c403418e-35cf-42ec-9060-c1f2e4d5997b' User entered 'None (0)'	System	02 Oct 2020 23:06:57
	System	02 Oct 2020 23:06:57

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:39', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c403418e-35cf-42ec-9060-c1f2e4d5997b' User entered 'None (0)'	System	02 Oct 2020 23:06:57
	System	02 Oct 2020 23:06:57

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:41', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c403418e-35cf-42ec-9060-c1f2e4d5997b' User entered 'None (0)'	System	02 Oct 2020 23:06:57
	System	02 Oct 2020 23:06:57

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:44', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c403418e-35cf-42ec-9060-c1f2e4d5997b' User entered 'None (0)'	System	02 Oct 2020 23:06:57
	System	02 Oct 2020 23:06:57

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:46', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c403418e-35cf-42ec-9060-c1f2e4d5997b' User entered 'None (0)'	System	02 Oct 2020 23:06:57
	System	02 Oct 2020 23:06:57

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:52', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c403418e-35cf-42ec-9060-c1f2e4d5997b' User entered 'No (N)'	System	02 Oct 2020 23:06:57
	System	02 Oct 2020 23:06:57

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-02T16:06:55', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'c403418e-35cf-42ec-9060-c1f2e4d5997b' User entered '02 Oct 2020 16:06'	System	02 Oct 2020 23:06:57
	System	02 Oct 2020 23:06:57

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 3'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:24:03', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '15988c47-2d01-4b94-a2ce-cec5ca53df00' User entered 'None (0)'	System	03 Oct 2020 23:24:28
	System	03 Oct 2020 23:24:28

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:24:06', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '15988c47-2d01-4b94-a2ce-cec5ca53df00' User entered 'None (0)'	System	03 Oct 2020 23:24:28
	System	03 Oct 2020 23:24:28

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:24:09', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '15988c47-2d01-4b94-a2ce-cec5ca53df00' User entered 'None (0)'	System	03 Oct 2020 23:24:28
	System	03 Oct 2020 23:24:28

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:24:11', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '15988c47-2d01-4b94-a2ce-cec5ca53df00' User entered 'None (0)'	System	03 Oct 2020 23:24:28
	System	03 Oct 2020 23:24:28

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:24:16', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '15988c47-2d01-4b94-a2ce-cec5ca53df00' User entered 'None (0)'	System	03 Oct 2020 23:24:28
	System	03 Oct 2020 23:24:28

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:24:18', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '15988c47-2d01-4b94-a2ce-cec5ca53df00' User entered 'None (0)'	System	03 Oct 2020 23:24:28
	System	03 Oct 2020 23:24:28

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:24:22', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '15988c47-2d01-4b94-a2ce-cec5ca53df00' User entered 'No (N)'	System	03 Oct 2020 23:24:28
	System	03 Oct 2020 23:24:28

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-03T16:24:26', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '15988c47-2d01-4b94-a2ce-cec5ca53df00' User entered '03 Oct 2020 16:24'	System	03 Oct 2020 23:24:28
	System	03 Oct 2020 23:24:28

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 4'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:46', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5b37eb22-e37a-4395-9b5b-1f095b2b8e64'	System	05 Oct 2020 09:34:20
User entered 'No interference with activity (1)'	System	05 Oct 2020 09:34:20

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:50', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5b37eb22-e37a-4395-9b5b-1f095b2b8e64' User entered 'None (0)'	System	05 Oct 2020 09:34:20
	System	05 Oct 2020 09:34:20

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:53', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5b37eb22-e37a-4395-9b5b-1f095b2b8e64' User entered 'None (0)'	System	05 Oct 2020 09:34:20
	System	05 Oct 2020 09:34:20

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:55', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5b37eb22-e37a-4395-9b5b-1f095b2b8e64' User entered 'None (0)'	System	05 Oct 2020 09:34:20
	System	05 Oct 2020 09:34:20

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:33:58', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5b37eb22-e37a-4395-9b5b-1f095b2b8e64' User entered 'None (0)'	System	05 Oct 2020 09:34:20
	System	05 Oct 2020 09:34:20

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:34:01', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5b37eb22-e37a-4395-9b5b-1f095b2b8e64' User entered 'None (0)'	System	05 Oct 2020 09:34:20
	System	05 Oct 2020 09:34:20

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:34:04', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5b37eb22-e37a-4395-9b5b-1f095b2b8e64' User entered 'No (N)'	System	05 Oct 2020 09:34:20
	System	05 Oct 2020 09:34:20

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T02:34:14', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '5b37eb22-e37a-4395-9b5b-1f095b2b8e64' User entered '05 Oct 2020 02:34'	System	05 Oct 2020 09:34:20
	System	05 Oct 2020 09:34:20

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 5'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:52', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cc2232f8-1954-44ef-b92a-75f426f439e6' User entered 'None (0)'	System	05 Oct 2020 22:25:15
	System	05 Oct 2020 22:25:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:54', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cc2232f8-1954-44ef-b92a-75f426f439e6' User entered 'None (0)'	System	05 Oct 2020 22:25:15
	System	05 Oct 2020 22:25:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:56', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cc2232f8-1954-44ef-b92a-75f426f439e6' User entered 'None (0)'	System	05 Oct 2020 22:25:15
	System	05 Oct 2020 22:25:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:24:58', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cc2232f8-1954-44ef-b92a-75f426f439e6' User entered 'None (0)'	System	05 Oct 2020 22:25:15
	System	05 Oct 2020 22:25:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:25:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cc2232f8-1954-44ef-b92a-75f426f439e6' User entered 'None (0)'	System	05 Oct 2020 22:25:15
	System	05 Oct 2020 22:25:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:25:03', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cc2232f8-1954-44ef-b92a-75f426f439e6' User entered 'None (0)'	System	05 Oct 2020 22:25:15
	System	05 Oct 2020 22:25:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:25:08', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cc2232f8-1954-44ef-b92a-75f426f439e6' User entered 'No (N)'	System	05 Oct 2020 22:25:15
	System	05 Oct 2020 22:25:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-05T15:25:12', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cc2232f8-1954-44ef-b92a-75f426f439e6' User entered '05 Oct 2020 15:25'	System	05 Oct 2020 22:25:15
	System	05 Oct 2020 22:25:15

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 6'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:31', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a40f3f6b-2548-4bc0-bb92-df32adc91dbe'	System	07 Oct 2020 01:45:53
User entered 'No interference with activity (1)'	System	07 Oct 2020 01:45:53

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a40f3f6b-2548-4bc0-bb92-df32adc91dbe' User entered 'None (0)'	System	07 Oct 2020 01:45:53
	System	07 Oct 2020 01:45:53

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:35', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a40f3f6b-2548-4bc0-bb92-df32adc91dbe' User entered 'None (0)'	System	07 Oct 2020 01:45:53
	System	07 Oct 2020 01:45:53

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:37', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a40f3f6b-2548-4bc0-bb92-df32adc91dbe' User entered 'None (0)'	System	07 Oct 2020 01:45:53
	System	07 Oct 2020 01:45:53

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:39', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a40f3f6b-2548-4bc0-bb92-df32adc91dbe' User entered 'None (0)'	System	07 Oct 2020 01:45:53
	System	07 Oct 2020 01:45:53

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:41', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a40f3f6b-2548-4bc0-bb92-df32adc91dbe' User entered 'None (0)'	System	07 Oct 2020 01:45:53
	System	07 Oct 2020 01:45:53

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:45', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a40f3f6b-2548-4bc0-bb92-df32adc91dbe' User entered 'No (N)'	System	07 Oct 2020 01:45:53
	System	07 Oct 2020 01:45:53

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-06T18:45:50', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'a40f3f6b-2548-4bc0-bb92-df32adc91dbe' User entered '06 Oct 2020 18:45'	System	07 Oct 2020 01:45:53
	System	07 Oct 2020 01:45:53

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	01 Oct 2020 23:29:14
User entered 'Day 7'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:36', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cb742af4-1a05-4cdb-90d2-b8222236507e' User entered 'None (0)'	System	08 Oct 2020 16:40:54
	System	08 Oct 2020 16:40:54

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:38', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cb742af4-1a05-4cdb-90d2-b8222236507e' User entered 'None (0)'	System	08 Oct 2020 16:40:54
	System	08 Oct 2020 16:40:54

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:39', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cb742af4-1a05-4cdb-90d2-b8222236507e' User entered 'None (0)'	System	08 Oct 2020 16:40:54
	System	08 Oct 2020 16:40:54

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:41', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cb742af4-1a05-4cdb-90d2-b8222236507e' User entered 'None (0)'	System	08 Oct 2020 16:40:54
	System	08 Oct 2020 16:40:54

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:42', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cb742af4-1a05-4cdb-90d2-b8222236507e' User entered 'None (0)'	System	08 Oct 2020 16:40:54
	System	08 Oct 2020 16:40:54

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:44', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cb742af4-1a05-4cdb-90d2-b8222236507e' User entered 'None (0)'	System	08 Oct 2020 16:40:54
	System	08 Oct 2020 16:40:54

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:47', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cb742af4-1a05-4cdb-90d2-b8222236507e' User entered 'No (N)'	System	08 Oct 2020 16:40:54
	System	08 Oct 2020 16:40:54

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-10-08T09:40:50', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'cb742af4-1a05-4cdb-90d2-b8222236507e' User entered '08 Oct 2020 09:40'	System	08 Oct 2020 16:40:54
	System	08 Oct 2020 16:40:54

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 23:29:14

US3642081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 23:29:14

US3642081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	09 Oct 2020 16:26:21

US3642081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '09 Oct 2020'	(b) (4) Nancy Tang (b) (4)	09 Oct 2020 16:26:21

US3642081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	09 Oct 2020 16:26:21

US3642081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Nancy Tang (b) (4)	09 Oct 2020 16:26:21

US3642081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	09 Oct 2020 16:26:25

US3642081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'I'	System	09 Oct 2020 16:26:25

US3642081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Oct 2020 16:27:53

US3642081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '17 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Oct 2020 16:27:53

US3642081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Oct 2020 16:27:53

US3642081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Oct 2020 16:27:53

US3642081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Oct 2020 16:27:58

US3642081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'I'	System	17 Oct 2020 16:27:58

US3642081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	24 Oct 2020 22:47:20

US3642081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '24 Oct 2020'	(b) (4) Nancy Tang (b) (4)	24 Oct 2020 22:47:20

US3642081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	24 Oct 2020 22:47:20

US3642081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Nancy Tang (b) (4)	24 Oct 2020 22:47:20

US3642081

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	24 Oct 2020 22:47:25

US3642081

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'I'	System	24 Oct 2020 22:47:25

US3642081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	02 Nov 2020 16:47:45

US3642081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '30 Oct 2020'	Son Do (b) (4)	02 Nov 2020 16:47:45

US3642081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Clinic (Clinic)'	Son Do (b) (4)	02 Nov 2020 16:47:45

US3642081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'VISIT3'	System	02 Nov 2020 16:47:45

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '30 Oct 2020'	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '13:41'	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered '30 Oct 2020 13:41'	System	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '98.1' F	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Oral (Oral)'	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '85'	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'bpm'	System	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '16'	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'breaths/min'	System	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '112'	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'mmHg'	System	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 03:34:09
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not clinically significant' (Site from System).	Colleen McLellan (b) (4) (b) (4)	05 Nov 2020 21:04:10
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Nov 2020 16:48:09
User entered '56'	Son Do (b) (4)	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'mmHg'	System	02 Nov 2020 16:48:09

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47

US3642081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47

US3642081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'No (N)' reason for change: Data Entry Error	Son Do (b) (4)	04 Nov 2020 17:03:35
User entered 'Yes (Y)'	Son Do (b) (4)	02 Nov 2020 16:48:20

US3642081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty; reason for change Data Entry Error	(b) (4)	
	Son Do (b) (4)	04 Nov 2020 17:03:35
User entered '30 Oct 2020'	Son Do (b) (4)	02 Nov 2020 16:48:20

US3642081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	02 Nov 2020 16:48:31

US3642081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '30 Oct 2020'	Son Do (b) (4)	02 Nov 2020 16:48:31

US3642081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '14:10'	Son Do (b) (4)	02 Nov 2020 16:48:31

US3642081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered '30 Oct 2020 14:10'	System	02 Nov 2020 16:48:31

US3642081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Son Do (b) (4)	02 Nov 2020 16:48:37

US3642081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:47
User entered 'I'	System	02 Nov 2020 16:48:37

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 64'	System	02 Sep 2020 22:58:34

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-05T17:59:56', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd3a5f1ce-ffad-4b10-b520-cf47eb3c223a' User entered 'No (N)'	System	06 Nov 2020 02:00:23
	System	06 Nov 2020 02:00:23

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-05T18:00:14', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd3a5f1ce-ffad-4b10-b520-cf47eb3c223a' User entered 'No (N)'	System	06 Nov 2020 02:00:23
	System	06 Nov 2020 02:00:23

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-05T18:00:22', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'd3a5f1ce-ffad-4b10-b520-cf47eb3c223a' User entered '05 Nov 2020 18:00:22'	System	06 Nov 2020 02:00:23
	System	06 Nov 2020 02:00:23

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 22:58:34

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 71'	System	02 Sep 2020 22:58:34

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-10T18:57:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '33ee206a-0e93-49ad-a317-0af49e79026a' User entered 'No (N)'	System	11 Nov 2020 02:57:19
	System	11 Nov 2020 02:57:19

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Have you been exposed to someone with 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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-10T18:57:09', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '33ee206a-0e93-49ad-a317-0af49e79026a' User entered 'No (N)'	System	11 Nov 2020 02:57:19
	System	11 Nov 2020 02:57:19

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-10T18:57:16', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '33ee206a-0e93-49ad-a317-0af49e79026a' User entered '10 Nov 2020 18:57:16'	System	11 Nov 2020 02:57:19
	System	11 Nov 2020 02:57:19

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 22:58:34

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered 'Day 78'	System	02 Sep 2020 22:58:34

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-16T06:44:25', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f3c92ebd-43a6-46ec-bc7f-988771a9bcc4' User entered 'No (N)'	System	16 Nov 2020 14:44:40
	System	16 Nov 2020 14:44:40

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-16T06:44:34', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f3c92ebd-43a6-46ec-bc7f-988771a9bcc4'	System	16 Nov 2020 14:44:40
User entered 'No (N)'	System	16 Nov 2020 14:44:40

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-16T06:44:38', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f3c92ebd-43a6-46ec-bc7f-988771a9bcc4' User entered '16 Nov 2020 06:44:38'	System	16 Nov 2020 14:44:40
	System	16 Nov 2020 14:44:40

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 22:58:34

US3642081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:12:06
Data entry locked.	System	02 Sep 2020 22:58:34
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 22:58:34

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-27T08:00:40', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0e830dcb-df7e-45fa-a79a-e8fface29612' User entered 'No (N)'	System	27 Nov 2020 16:00:55
	System	27 Nov 2020 16:00:55

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-27T08:00:47', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0e830dcb-df7e-45fa-a79a-e8fface29612' User entered 'No (N)'	System	27 Nov 2020 16:00:55
	System	27 Nov 2020 16:00:55

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-11-27T08:00:51', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '0e830dcb-df7e-45fa-a79a-e8fface29612' User entered '27 Nov 2020 08:00:51'	System	27 Nov 2020 16:00:55
	System	27 Nov 2020 16:00:55

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-04T02:35:20', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '00ce2f73-a052-46c9-a935-52a4d501473f' User entered 'No (N)'	System	04 Dec 2020 10:35:36
	System	04 Dec 2020 10:35:36

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-04T02:35:27', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '00ce2f73-a052-46c9-a935-52a4d501473f' User entered 'No (N)'	System	04 Dec 2020 10:35:36

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-04T02:35:34', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '00ce2f73-a052-46c9-a935-52a4d501473f' User entered '04 Dec 2020 02:35:34'	System	04 Dec 2020 10:35:36
	System	04 Dec 2020 10:35:36

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-11T05:32:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9f2ce12d-5d89-4d54-9de8-6d84b1088cf4' User entered 'No (N)'	System	11 Dec 2020 13:33:05
	System	11 Dec 2020 13:33:05

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-11T05:32:53', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9f2ce12d-5d89-4d54-9de8-6d84b1088cf4'	System	11 Dec 2020 13:33:05
User entered 'No (N)'	System	11 Dec 2020 13:33:05

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-11T05:33:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9f2ce12d-5d89-4d54-9de8-6d84b1088cf4' User entered '11 Dec 2020 05:33:00'	System	11 Dec 2020 13:33:05
	System	11 Dec 2020 13:33:05

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-18T07:41:33', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'ad03bfa3-c111-4c88-add0-70853ebd9742' User entered 'No (N)'	System	18 Dec 2020 15:41:52
	System	18 Dec 2020 15:41:52

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-18T07:41:41', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'ad03bfa3-c111-4c88-add0-70853ebd9742' User entered 'No (N)'	System	18 Dec 2020 15:41:52
	System	18 Dec 2020 15:41:52

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-18T07:41:48', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'ad03bfa3-c111-4c88-add0-70853ebd9742' User entered '18 Dec 2020 07:41:48'	System	18 Dec 2020 15:41:52
	System	18 Dec 2020 15:41:52

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-25T08:27:20', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e2dd94db-d15c-4319-a4f7-5b94f5e73252'	System	25 Dec 2020 16:27:55
User entered 'Yes (Y)'	System	25 Dec 2020 16:27:55

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-25T08:27:27', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e2dd94db-d15c-4319-a4f7-5b94f5e73252'	System	25 Dec 2020 16:27:55
User entered 'No (N)'	System	25 Dec 2020 16:27:55

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-25T08:27:34', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e2dd94db-d15c-4319-a4f7-5b94f5e73252'	System	25 Dec 2020 16:27:55
User entered 'No (N)'	System	25 Dec 2020 16:27:55

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-25T08:27:43', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e2dd94db-d15c-4319-a4f7-5b94f5e73252'	System	25 Dec 2020 16:27:55
User entered 'No (N)'	System	25 Dec 2020 16:27:55

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2020-12-25T08:27:51', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'e2dd94db-d15c-4319-a4f7-5b94f5e73252' User entered '25 Dec 2020 08:27:51'	System	25 Dec 2020 16:27:55
	System	25 Dec 2020 16:27:55

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-01T06:25:29', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '92c5b01c-430e-4b2f-ab44-8c69bdf5465b' User entered 'No (N)'	System	01 Jan 2021 14:25:48
	System	01 Jan 2021 14:25:48

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-01T06:25:40', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '92c5b01c-430e-4b2f-ab44-8c69bdf5465b' User entered 'No (N)'	System	01 Jan 2021 14:25:48
	System	01 Jan 2021 14:25:48

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-01T06:25:44', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '92c5b01c-430e-4b2f-ab44-8c69bdf5465b' User entered '01 Jan 2021 06:25:44'	System	01 Jan 2021 14:25:48
	System	01 Jan 2021 14:25:48

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-08T03:41:42', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '894a519c-f7cc-4d29-86f8-1d6f340e19fd' User entered 'No (N)'	System	08 Jan 2021 11:42:14
	System	08 Jan 2021 11:42:14

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-08T03:42:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '894a519c-f7cc-4d29-86f8-1d6f340e19fd' User entered 'No (N)'	System	08 Jan 2021 11:42:14

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-08T03:42:11', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '894a519c-f7cc-4d29-86f8-1d6f340e19fd' User entered '08 Jan 2021 03:42:11'	System	08 Jan 2021 11:42:14

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-15T18:42:10', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'b04df0af-fe4c-4b76-a303-740d29275c98'	System	16 Jan 2021 02:42:27
User entered 'No (N)'	System	16 Jan 2021 02:42:27

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-15T18:42:18', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'b04df0af-fe4c-4b76-a303-740d29275c98'	System	16 Jan 2021 02:42:27
User entered 'No (N)'	System	16 Jan 2021 02:42:27

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-15T18:42:24', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'b04df0af-fe4c-4b76-a303-740d29275c98' User entered '15 Jan 2021 18:42:24'	System	16 Jan 2021 02:42:27

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-22T00:01:22', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f5cd268b-8270-4bbc-82e6-449472655c2e' User entered 'No (N)'	System	22 Jan 2021 08:01:36
	System	22 Jan 2021 08:01:36

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-22T00:01:27', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f5cd268b-8270-4bbc-82e6-449472655c2e' User entered 'No (N)'	System	22 Jan 2021 08:01:36

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-01-22T00:01:31', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'f5cd268b-8270-4bbc-82e6-449472655c2e' User entered '22 Jan 2021 00:01:31'	System	22 Jan 2021 08:01:36
	System	22 Jan 2021 08:01:36

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-01T18:53:37', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9fd997d5-9f75-4456-9d89-63a2d27d70d8' User entered 'Yes (Y)'	System	02 Feb 2021 02:54:48
	System	02 Feb 2021 02:54:48

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-01T18:53:42', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9fd997d5-9f75-4456-9d89-63a2d27d70d8' User entered 'No (N)'	System	02 Feb 2021 02:54:48

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-01T18:53:47', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9fd997d5-9f75-4456-9d89-63a2d27d70d8' User entered 'No (N)'	System	02 Feb 2021 02:54:48

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-01T18:54:13', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9fd997d5-9f75-4456-9d89-63a2d27d70d8' User entered 'No (N)'	System	02 Feb 2021 02:54:48
	System	02 Feb 2021 02:54:48

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-01T18:54:46', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9fd997d5-9f75-4456-9d89-63a2d27d70d8' User entered '01 Feb 2021 18:54:46'	System	02 Feb 2021 02:54:48
	System	02 Feb 2021 02:54:48

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-05T05:04:30', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '41d36e22-709e-42da-a7d8-c53f727540c1' User entered 'No (N)'	System	05 Feb 2021 13:04:52
	System	05 Feb 2021 13:04:52

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-05T05:04:36', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '41d36e22-709e-42da-a7d8-c53f727540c1' User entered 'No (N)'	System	05 Feb 2021 13:04:52
	System	05 Feb 2021 13:04:52

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-05T05:04:48', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '41d36e22-709e-42da-a7d8-c53f727540c1' User entered '05 Feb 2021 05:04:48'	System	05 Feb 2021 13:04:52
	System	05 Feb 2021 13:04:52

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-12T04:32:01', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1e43fd4d-53fe-4676-aa20-756b6ce46a74' User entered 'No (N)'	System	12 Feb 2021 12:32:50
	System	12 Feb 2021 12:32:50

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-12T04:32:12', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1e43fd4d-53fe-4676-aa20-756b6ce46a74'	System	12 Feb 2021 12:32:50
User entered 'No (N)'	System	12 Feb 2021 12:32:50

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-12T04:32:23', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '1e43fd4d-53fe-4676-aa20-756b6ce46a74' User entered '12 Feb 2021 04:32:23'	System	12 Feb 2021 12:32:50
	System	12 Feb 2021 12:32:50

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-22T17:59:25', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '7ebdbf1b-612a-4b0a-8abd-e1a8c7fa4741' User entered 'No (N)'	System	26 Feb 2021 10:12:26
	System	26 Feb 2021 10:12:26

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-22T17:59:29', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '7ebdbf1b-612a-4b0a-8abd-e1a8c7fa4741' User entered 'No (N)'	System	26 Feb 2021 10:12:26

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-22T17:59:35', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '7ebdbf1b-612a-4b0a-8abd-e1a8c7fa4741' User entered '22 Feb 2021 17:59:35'	System	26 Feb 2021 10:12:26
	System	26 Feb 2021 10:12:26

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-26T02:12:30-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'ffe4650e-0ecc-4a0a-a250-0a852ca65c85'	System	26 Feb 2021 10:12:44
User entered 'No (N)'	System	26 Feb 2021 10:12:44

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-26T02:12:37-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'ffe4650e-0ecc-4a0a-a250-0a852ca65c85'	System	26 Feb 2021 10:12:44
User entered 'No (N)'	System	26 Feb 2021 10:12:44

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-02-26T02:12:42-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'ffe4650e-0ecc-4a0a-a250-0a852ca65c85' User entered '26 Feb 2021 10:12:42'	System	26 Feb 2021 10:12:44
	System	26 Feb 2021 10:12:44

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-05T04:25:22-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '439c60c8-b01e-4168-a1e3-239150f45d68'	System	05 Mar 2021 12:26:53
User entered 'No (N)'	System	05 Mar 2021 12:26:53

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-05T04:26:45-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '439c60c8-b01e-4168-a1e3-239150f45d68'	System	05 Mar 2021 12:26:53
User entered 'No (N)'	System	05 Mar 2021 12:26:53

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-05T04:26:51-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '439c60c8-b01e-4168-a1e3-239150f45d68' User entered '05 Mar 2021 04:26:51'	System	05 Mar 2021 12:26:53
	System	05 Mar 2021 12:26:53

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-12T00:02:34-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '90f9c214-d3d9-4c85-aa80-d1648636f93b'	System	12 Mar 2021 08:02:53
User entered 'No (N)'	System	12 Mar 2021 08:02:53

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-12T00:02:45-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '90f9c214-d3d9-4c85-aa80-d1648636f93b'	System	12 Mar 2021 08:02:53
User entered 'No (N)'	System	12 Mar 2021 08:02:53

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-12T00:02:50-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '90f9c214-d3d9-4c85-aa80-d1648636f93b' User entered '12 Mar 2021 00:02:50'	System	12 Mar 2021 08:02:53
	System	12 Mar 2021 08:02:53

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-22T17:59:28-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '902b8804-0e84-4c09-b450-9713a4e1e7e8'	System	23 Mar 2021 00:59:42
User entered 'No (N)'	System	23 Mar 2021 00:59:42

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-22T17:59:35-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '902b8804-0e84-4c09-b450-9713a4e1e7e8'	System	23 Mar 2021 00:59:42
User entered 'No (N)'	System	23 Mar 2021 00:59:42

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-22T17:59:39-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '902b8804-0e84-4c09-b450-9713a4e1e7e8' User entered '22 Mar 2021 17:59:39'	System	23 Mar 2021 00:59:42

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-26T07:59:42-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '101a2967-95fb-4cdb-8e6d-958e692e229f'	System	26 Mar 2021 14:59:54
User entered 'No (N)'	System	26 Mar 2021 14:59:54

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-26T07:59:45-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '101a2967-95fb-4cdb-8e6d-958e692e229f'	System	26 Mar 2021 14:59:54
User entered 'No (N)'	System	26 Mar 2021 14:59:54

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-26T07:59:50-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '101a2967-95fb-4cdb-8e6d-958e692e229f' User entered '26 Mar 2021 07:59:50'	System	26 Mar 2021 14:59:54
	System	26 Mar 2021 14:59:54

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-02T03:15:22-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '807a7a77-86a2-4c69-b854-a91b9b8d0feb' User entered 'Yes (Y)'	System	02 Apr 2021 10:16:41
	System	02 Apr 2021 10:16:41

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-02T03:15:38-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '807a7a77-86a2-4c69-b854-a91b9b8d0feb' User entered 'No (N)'	System	02 Apr 2021 10:16:41
	System	02 Apr 2021 10:16:41

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-02T03:15:46-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '807a7a77-86a2-4c69-b854-a91b9b8d0feb' User entered 'No (N)'	System	02 Apr 2021 10:16:41
	System	02 Apr 2021 10:16:41

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-02T03:15:57-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '807a7a77-86a2-4c69-b854-a91b9b8d0feb' User entered 'Yes (Y)'	System	02 Apr 2021 10:16:41
	System	02 Apr 2021 10:16:41

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Please 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-02T03:16:09-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '807a7a77-86a2-4c69-b854-a91b9b8d0feb'	System	02 Apr 2021 10:16:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Apr 2021 10:16:41

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-02T03:16:31-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '807a7a77-86a2-4c69-b854-a91b9b8d0feb' User entered '02 Apr 2021 03:16:31'	System	02 Apr 2021 10:16:41
	System	02 Apr 2021 10:16:41

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-09T07:23:26-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '887a68a2-7991-47e2-80b2-478292a94143'	System	13 Apr 2021 18:19:17
User entered 'No (N)'	System	13 Apr 2021 18:19:17

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-09T07:23:31-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '887a68a2-7991-47e2-80b2-478292a94143'	System	13 Apr 2021 18:19:17
User entered 'No (N)'	System	13 Apr 2021 18:19:17

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-09T07:23:37-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '887a68a2-7991-47e2-80b2-478292a94143'	System	13 Apr 2021 18:19:17
User entered '09 Apr 2021 07:23:37'	System	13 Apr 2021 18:19:17

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-16T16:56:55-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'afc75878-ec95-499c-a897-70abecf3326c' User entered 'No (N)'	System	16 Apr 2021 23:57:07
	System	16 Apr 2021 23:57:07

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-16T16:56:59-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'afc75878-ec95-499c-a897-70abecf3326c' User entered 'No (N)'	System	16 Apr 2021 23:57:07
	System	16 Apr 2021 23:57:07

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-16T16:57:03-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: 'afc75878-ec95-499c-a897-70abecf3326c' User entered '16 Apr 2021 16:57:03'	System	16 Apr 2021 23:57:07
	System	16 Apr 2021 23:57:07

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-23T03:03:36-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '949b1911-5cac-44de-b576-fb2e7b6145ec' User entered 'No (N)'	System	30 Apr 2021 09:19:43
	System	30 Apr 2021 09:19:43

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-23T03:03:44-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '949b1911-5cac-44de-b576-fb2e7b6145ec' User entered 'No (N)'	System	30 Apr 2021 09:19:43

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-23T03:03:51-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '949b1911-5cac-44de-b576-fb2e7b6145ec' User entered '23 Apr 2021 03:03:51'	System	30 Apr 2021 09:19:43
	System	30 Apr 2021 09:19:43

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-30T02:19:49-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '40aba888-24d5-4c74-b4fc-f9f927915887'	System	30 Apr 2021 09:20:02
User entered 'No (N)'	System	30 Apr 2021 09:20:02

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

Have you been exposed to someone with 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 (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-30T02:19:53-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '40aba888-24d5-4c74-b4fc-f9f927915887'	System	30 Apr 2021 09:20:02
User entered 'No (N)'	System	30 Apr 2021 09:20:02

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-04-30T02:19:59-07:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '40aba888-24d5-4c74-b4fc-f9f927915887'	System	30 Apr 2021 09:20:02
User entered '30 Apr 2021 02:19:59'	System	30 Apr 2021 09:20:02

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:59:29

US3642081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:29
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:59:29

US3642081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:14:06

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 19:02:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-05T04:27:08-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9ed9ff0d-4aeb-4cac-96f4-6712d03c4d0d'	System	05 Mar 2021 12:27:24
User entered 'No (N)'	System	05 Mar 2021 12:27:24

US3642081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:14:06

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4FADC8CD-9092-453E-870E-746D6FAFBEEE)', Time: '2021-03-05T04:27:22-08:00', User OID: 'PatientReportedOutcome (US3642081)', ODM File OID: '9ed9ff0d-4aeb-4cac-96f4-6712d03c4d0d' User entered '05 Mar 2021 04:27:22'	System	05 Mar 2021 12:27:24
	System	05 Mar 2021 12:27:24

US3642081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	27 Nov 2020 21:09:16

US3642081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	27 Nov 2020 21:09:40
answered by data change (Site from System).		
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	27 Nov 2020 21:09:40
answered by data change (Site from System).		
User entered '27 Nov 2020' reason for change: Data Entry Error	Nancy Tang (b) (4)	27 Nov 2020 21:09:40
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Nov 2020 21:09:16
User entered '27 Oct 2020'	Nancy Tang (b) (4)	27 Nov 2020 21:09:16

US3642081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	27 Nov 2020 21:09:16

US3642081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	(b) (4) Nancy Tang (b) (4)	27 Nov 2020 21:09:16

US3642081

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	27 Nov 2020 21:09:21

US3642081

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:51:32
User entered 'I'	System	27 Nov 2020 21:09:21

US3642081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	08 Jan 2021 19:05:46

US3642081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '08 Jan 2021'	Jennifer Morales (b) (4)	08 Jan 2021 19:05:46

US3642081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	08 Jan 2021 19:05:46

US3642081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
Signature has been broken.	Megan Loughran (b) (4)	15 Mar 2021 19:07:32
User entered 'call made out of window d/t staff error.' reason for change: Data Entry Error	Megan Loughran (b) (4)	15 Mar 2021 19:07:32
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	Jennifer Morales (b) (4)	08 Jan 2021 19:05:46

US3642081

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	08 Jan 2021 19:05:51

US3642081

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered 'I'	System	08 Jan 2021 19:05:51

US3642081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	30 Jan 2021 01:57:19

US3642081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '29 Jan 2021'	(b) (4) Lindsey Woronicz (b) (4)	30 Jan 2021 01:57:19

US3642081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	30 Jan 2021 01:57:19

US3642081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	30 Jan 2021 01:57:19

US3642081

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	30 Jan 2021 01:57:27

US3642081

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered 'I'	System	30 Jan 2021 01:57:27

US3642081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4)	05 Mar 2021 19:08:01

US3642081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
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) System	05 Mar 2021 19:08:16
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 by data change (Site from System).	System	05 Mar 2021 19:08:16
User entered '01 Mar 2021' reason for change: Data Entry Error	Jennifer Morales (b) (4) (b) (4)	05 Mar 2021 19:08:16
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	05 Mar 2021 19:08:01
User entered '05 Mar 2021'	Jennifer Morales (b) (4) (b) (4)	05 Mar 2021 19:08:01

US3642081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	05 Mar 2021 19:08:01

US3642081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered empty.	Jennifer Morales (b) (4)	05 Mar 2021 19:08:01

US3642081

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	05 Mar 2021 19:08:23

US3642081

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered 'I'	System	05 Mar 2021 19:08:23

US3642081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Yes (Y)'	Son Do (b) (4)	18 Mar 2021 14:51:15

US3642081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '16 Mar 2021'	Son Do (b) (4)	18 Mar 2021 14:51:15

US3642081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Clinic (Clinic)'	Son Do (b) (4)	18 Mar 2021 14:51:15

US3642081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered 'VISIT4'	System	18 Mar 2021 14:51:15

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered empty.	System	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	(b) (4) Benjamin Hull (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	(b) (4) Benjamin Hull (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered empty.	System	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered empty.	System	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered empty.	System	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered empty.	System	30 Mar 2021 19:55:30

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59

US3642081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59

US3642081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'No (N)'	Son Do (b) (4)	18 Mar 2021 14:51:21

US3642081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:51:21

US3642081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Yes (Y)'	Son Do (b) (4)	18 Mar 2021 14:51:36

US3642081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '16 Mar 2021'	Son Do (b) (4)	18 Mar 2021 14:51:36

US3642081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '15:15'	Son Do (b) (4)	18 Mar 2021 14:51:36

US3642081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered '16 Mar 2021 15:15'	System	18 Mar 2021 14:51:36

US3642081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Yes (Y)'	Son Do (b) (4)	18 Mar 2021 14:51:45

US3642081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:59
User entered 'I'	System	18 Mar 2021 14:51:45

US3642081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 17:09:22

US3642081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:16
	(b) (4)	
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 17:09:22

US3642081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:09:22

US3642081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:16
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 17:09:22

US3642081

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 17:09:27

US3642081

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 17:09:27

US3642081

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

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 18:07:37

US3642081

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

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Jan 2021'	Son Do (b) (4)	19 Jan 2021 18:07:37

US3642081

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

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Clinic (Clinic)'	Son Do (b) (4)	19 Jan 2021 18:07:37

US3642081

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

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 18:07:37

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Jan 2021'	Son Do (b) (4)	19 Jan 2021 18:07:56

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:13:17
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:26:18

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 18:07:56

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:13:17
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 18:26:18

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
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 11:44:06
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 22:56:43
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	19 Jan 2021 18:07:56
User entered '08 Jan 2021'	Son Do (b) (4)	19 Jan 2021 18:07:56

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Placebo (Placebo)'	Son Do (b) (4)	19 Jan 2021 18:07:56

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:54:02
User entered 'Placebo (Placebo)'	Son Do (b) (4)	19 Jan 2021 18:07:56

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:54:02
User entered 'Placebo (Placebo)'	Son Do (b) (4)	19 Jan 2021 18:07:56

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 18:07:56

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '1'	System	19 Jan 2021 18:07:56

US3642081

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'I'	System	19 Jan 2021 18:07:56

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	19 Jan 2021 18:08:41
DataPoint set to visible.	System	19 Jan 2021 18:07:56

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	19 Jan 2021 18:08:41
DataPoint set to visible.	System	19 Jan 2021 18:07:56

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Jan 2021'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '10:12'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '16 Jan 2021 10:12'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '98.5' F	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Oral (Oral)'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '91'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'bpm'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '17'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'breaths/min'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '121'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '69'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered empty.	System	19 Jan 2021 18:08:41
DataPoint set to visible.	System	19 Jan 2021 18:07:56

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Jan 2021'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '11:40'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '16 Jan 2021 11:40'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '98.2' F	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Oral (Oral)'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '74'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'bpm'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '18'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'breaths/min'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '127'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '77'	Son Do (b) (4)	19 Jan 2021 18:08:41

US3642081

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	19 Jan 2021 18:08:41

US3642081

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	Son Do (b) (4)	19 Jan 2021 18:08:46

US3642081

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	Son Do (b) (4)	19 Jan 2021 18:08:46

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 18:09:08
User entered 'Yes (Y)' reason for change: Data Entry Error	System	19 Jan 2021 18:09:08
User opened query 'Data is required. Please complete.' (Site from System).	Son Do (b) (4)	19 Jan 2021 18:09:02
User entered empty.	System	19 Jan 2021 18:09:02

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	Son Do (b) (4)	19 Jan 2021 18:09:02

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	Son Do (b) (4)	19 Jan 2021 18:09:02

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mRNA-1273'	System	19 Jan 2021 18:09:08
User entered empty.	System	19 Jan 2021 18:09:02
DataPoint set to visible.	System	19 Jan 2021 18:07:56

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Jan 2021'	Son Do (b) (4)	19 Jan 2021 18:09:02

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '11:14'	Son Do (b) (4)	19 Jan 2021 18:09:02

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '16 Jan 2021 11:14'	System	19 Jan 2021 18:09:02

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
Signature has been broken.	Son Do (b) (4)	17 Feb 2021 16:33:40
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Son Do (b) (4)	17 Feb 2021 16:33:40
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Right Arm (RIGHT ARM)'	Son Do (b) (4)	19 Jan 2021 18:09:02

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'ONCE'	System	19 Jan 2021 18:09:08
User entered empty.	System	19 Jan 2021 18:09:02

US3642081

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

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 18:09:08
User entered empty.	System	19 Jan 2021 18:09:02

US3642081

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 18:09:21

US3642081

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Jan 2021'	Son Do (b) (4)	19 Jan 2021 18:09:21

US3642081

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '10:51'	Son Do (b) (4)	19 Jan 2021 18:09:21

US3642081

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '16 Jan 2021 10:51'	System	19 Jan 2021 18:09:21

US3642081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 18:09:31

US3642081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Jan 2021'	Son Do (b) (4)	19 Jan 2021 18:09:31

US3642081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:14:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '10:53'	Son Do (b) (4)	19 Jan 2021 18:09:31

US3642081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:14:06

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '16 Jan 2021 10:53'	System	19 Jan 2021 18:09:31

US3642081

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

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 18:09:36

US3642081

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

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'I'	System	19 Jan 2021 18:09:36

US3642081

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:14
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	26 Jan 2021 17:11:08

US3642081

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:14
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered '25 Jan 2021'	Jennifer Morales (b) (4)	26 Jan 2021 17:11:08

US3642081

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:14
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	26 Jan 2021 17:11:08

US3642081

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:14
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered empty.	Jennifer Morales (b) (4)	26 Jan 2021 17:11:08

US3642081

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:14
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:41
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4)	26 Jan 2021 17:11:14

US3642081

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:14
User entered 'I'	System	26 Jan 2021 17:11:14

US3642081

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:14
User entered '1'	System	26 Jan 2021 17:11:14
DataPoint set to visible.	System	26 Jan 2021 17:11:14

US3642081

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered 'Yes (Y)'	Son Do (b) (4)	17 Feb 2021 16:29:20

US3642081

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered '13 Feb 2021'	Son Do (b) (4)	17 Feb 2021 16:29:20

US3642081

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered 'Clinic (Clinic)'	Son Do (b) (4)	17 Feb 2021 16:29:20

US3642081

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'OLD29'	System	17 Feb 2021 16:29:20

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered 'Yes (Y)'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '13 Feb 2021'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '10:19'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '13 Feb 2021 10:19'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '98.7' F	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered 'Oral (Oral)'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered empty.	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '82'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'bpm'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '17'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'breaths/min'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '108'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '68'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered 'Yes (Y)'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '13 Feb 2021'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '11:47'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '13 Feb 2021 11:47'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '98.8' F	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered 'Oral (Oral)'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered empty.	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '77'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'bpm'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '17'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'breaths/min'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User entered '103'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:44
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:50:36
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'BP not clinically significant.' (Site from System).	Benjamin Hull (b) (4) (b) (4)	04 Mar 2021 19:14:59
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Feb 2021 16:30:08
User entered '58'	Son Do (b) (4)	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mmHg'	System	17 Feb 2021 16:30:08

US3642081

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered 'No (N)'	Son Do (b) (4)	17 Feb 2021 16:30:16

US3642081

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered empty.	Son Do (b) (4)	17 Feb 2021 16:30:16

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered 'Yes (Y)'	Son Do (b) (4)	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered empty.	Son Do (b) (4)	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

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 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered empty.	Son Do (b) (4)	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'mRNA-1273'	System	17 Feb 2021 16:30:28
DataPoint set to visible.	System	26 Jan 2021 17:11:14

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered '13 Feb 2021'	Son Do (b) (4)	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered '11:07'	Son Do (b) (4)	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered '13 Feb 2021 11:07'	System	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	17 Feb 2021 16:33:40
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	17 Feb 2021 16:33:40
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	17 Feb 2021 16:30:28
User entered 'Left Arm (LEFT ARM)'	Son Do (b) (4)	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'ONCE'	System	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 16:30:28

US3642081

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:49
User entered 'Yes (Y)'	Son Do (b) (4)	17 Feb 2021 16:33:22

US3642081

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:14:11
User entered 'I'	System	17 Feb 2021 16:33:22

US3642081

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	20 Feb 2021 19:41:52

US3642081

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered '20 Feb 2021'	(b) (4) Colleen McLellan (b) (4)	20 Feb 2021 19:41:52

US3642081

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	20 Feb 2021 19:41:52

US3642081

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered empty.	Colleen McLellan (b) (4)	20 Feb 2021 19:41:52

US3642081

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:53
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	20 Feb 2021 19:41:58

US3642081

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:20
User entered 'I'	System	20 Feb 2021 19:41:58

US3642081

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Yes (Y)'	Son Do (b) (4)	18 Mar 2021 14:52:08

US3642081

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '16 Mar 2021'	Son Do (b) (4)	18 Mar 2021 14:52:08

US3642081

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Clinic (Clinic)'	Son Do (b) (4)	18 Mar 2021 14:52:08

US3642081

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User entered 'OLD57'	System	18 Mar 2021 14:52:08

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'No (N)'	(b) (4) Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User entered empty.	System	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User entered empty.	System	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User entered empty.	System	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User entered empty.	System	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User entered empty.	System	18 Mar 2021 14:52:16

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19

US3642081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19

US3642081

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'No (N)'	Son Do (b) (4)	18 Mar 2021 14:52:21

US3642081

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	Son Do (b) (4)	18 Mar 2021 14:52:21

US3642081

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Yes (Y)'	Son Do (b) (4)	18 Mar 2021 14:52:33

US3642081

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '16 Mar 2021'	Son Do (b) (4)	18 Mar 2021 14:52:33

US3642081

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '15:15'	Son Do (b) (4)	18 Mar 2021 14:52:33

US3642081

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:19
User entered '16 Mar 2021 15:15'	System	18 Mar 2021 14:52:33

US3642081

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:14:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:59
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify. Thank you! ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 07:37:03
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse event recorded corresponding page. Please review and update accordingly. else clarify. Thank you! ' answered with 'this question has been changed to yes' (Site from DM).	Megan Loughran (b) (4) (b) (4)	13 Apr 2021 19:49:08
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	13 Apr 2021 19:48:54
User entered 'Yes (Y)' reason for change: New Information	Megan Loughran (b) (4) (b) (4)	13 Apr 2021 19:48:54
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify. Thank you! ' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 05:09:42
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:28:15
Signature has been broken.	Son Do (b) (4)	29 Mar 2021 17:05:38
User entered 'No (N)' reason for change: New Information	Son Do (b) (4)	29 Mar 2021 17:05:38
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:40:44
Signature has been broken.	(b) (4), (b) (6)	22 Feb 2021 23:22:44
User entered 'Yes (Y)' reason for change: New Information		22 Feb 2021 23:22:44
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:53:08

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered 'USA-US109-2021-mRNA-1273-P301000012'	(b) (4) System	05 Apr 2021 16:03:44
User entered 'New'	(b) (4), (b) (6)	05 Apr 2021 16:03:44

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:06:02
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' answered with 'this is the exact term used for the diagnosis on the hospital record; no formal underlying condition was provided. ' (Site from Safety).	Megan Loughran (b) (4)	13 Apr 2021 17:42:45
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 11:16:31
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Epigastric pain - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 20:32:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 20:32:37
Data point term sent to Coder	System	02 Apr 2021 20:31:28
User entered 'EPIGASTRIC PAIN'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '28 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:31:14

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '29 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:31:14

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '1'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '28 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '29 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	02 Apr 2021 20:31:29
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	02 Apr 2021 20:31:29
User entered empty; reason for change Data Entry Error	Colleen McLellan (b) (4)	02 Apr 2021 20:31:29
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	02 Apr 2021 20:31:14
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 20:31:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 20:31:42
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	02 Apr 2021 20:31:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 20:31:14
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '1'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14
	(b) (4)	

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:59
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:06:16
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'this information has been added to the narrative. ' (Site from Safety).	Megan Loughran (b) (4) (b) (4)	13 Apr 2021 21:06:10
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	13 Apr 2021 21:06:00
User entered 'PATIENT EXPERIENCED SHARP NON-RADIATING MID EPIGASTRIC PAIN ON THE MORNING OF 28MAR2020. SHE PRESENTED TO THE ER AND WAS WORKED UP FOR APPENDICITIS AND ADMITTED INPATIENT TO A MEDICAL/SURGICAL UNIT. SHE WAS MADE NPO, GIVEN IV ANTIBIOTICS AND HAD AN ABDOMINAL CT. ABDOMINAL CT SHOWED PROBABLE APPENDICITIS BUT DID NOT WARRANT SURGICAL INVENTION. BY HOSPITAL LATE AFTERNOON 29MAR2020 THE PATIENT WAS ABLE TO TOLERATE A REGULAR DIET, PAIN WAS RESOLVED, AND ABDOMINAL ASSESSMENT WAS BENIGN. SHE WAS DISCHARGED HOME ON PO ANTIBIOTICS WITH STRICT RETURN TO ER PRECAUTIONS SHOULD EPIGASTRIC PAIN RETURN. SHE WILL FOLLOW UP WITH GI IN LATE APRIL2021. While in hospital, patient underwent routine covid-19 testing on 29mar2020. results were negative.' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	13 Apr 2021 21:06:00
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 11:16:41

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
User entered 'Patient experienced sharp non-radiating mid epigastric pain on the morning of 28MAR2020. She presented to the ER and was worked up for appendicitis and admitted inpatient to a medical/surgical unit. She was made NPO, given IV antibiotics and had an abdominal CT. Abdominal CT showed probable appendicitis but did not warrant surgical invention. By hospital late afternoon 29MAR2020 the patient was able to tolerate a regular diet, pain was resolved, and abdominal assessment was benign. She was discharged home on PO antibiotics with strict return to ER precautions should epigastric pain return. She will follow up with GI in late April2021.'	Colleen McLellan (b) (4)	02 Apr 2021 20:31:14

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 20:31:14

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 20:31:14

US3642081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 20:31:14

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 07:21:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 07:21:47
Data point term sent to Coder	System	22 Apr 2021 22:42:34
User entered 'SHINGLES INFECTION'	(b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User entered empty.	System	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User entered empty.	System	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'Subject reports that on 26JAN2021she started to develop a rash on her bottom. The rash persisted for a few days, so she decided to follow up with her PCP. Her PCP provided confirmation that she was experiencing a shingles infection and prescribed her Valacyclovir to treat the Shingles. The infection resolved the 09FEB2021 and she has had no issues since.'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User entered '0'	System	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18
User entered 'I'	System	22 Apr 2021 22:42:12

US3642081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:15:18

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:50
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User closed query 'Per CDM: Responses noted on Diary Dose 2, log line 5, 7. eDiary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Conmed page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 04:23:46
Query 'Per CDM: Responses noted on Diary Dose 2, log line 5, 7. eDiary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Conmed page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' answered with 'Per source.Conmed was taken for Migraine headache pain and recorded in conmeds.' (Site from DM).	Nancy Tang (b) (4)	05 Feb 2021 23:33:39
User opened query 'Per CDM: Responses noted on Diary Dose 2, log line 5, 7. eDiary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Conmed page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:59:34
User entered 'Yes (Y)'	Son Do (b) (4)	17 Sep 2020 17:50:35

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
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)	17 Sep 2020 17:53:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:53:42
Data point term sent to Coder	System	17 Sep 2020 17:52:18
User entered 'atorvastatin'	Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'hypercholesterolemia'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '20'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'UN UNK 2018'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '0'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:51:29

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 17:53:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:53:42
Data point term sent to Coder	System	17 Sep 2020 17:52:18
User entered 'vitamin d'	Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'vitamin d deficiency'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '2000'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'IU (IU)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'UN UNK 2015'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '0'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:52:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 05:50:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 05:50:43
Data point term sent to Coder	System	17 Sep 2020 17:53:20
User entered 'multivitamin centrum'	Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'general health'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '1'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'tablet (TABLET)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'UN UNK 2010'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '0'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:52:31

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Feb 2021 23:33:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 23:33:53
Data point term sent to Coder Coding entries removed.	System Nancy Tang (b) (4)	05 Feb 2021 23:33:43 05 Feb 2021 23:32:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 20:50:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 20:50:41
Data point term sent to Coder User entered 'advil'	System Son Do (b) (4)	17 Sep 2020 17:53:23 17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
	(b) (4)	
User entered 'MIGRAINE HEADACHES' reason for change: Data Entry Error	Nancy Tang (b) (4)	05 Feb 2021 23:32:59
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.' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 01:29:40
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).		17 Nov 2020 01:28:35
User entered 'migrains'	Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '200'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'as needed (PRN)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'UN UNK 1990'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '0'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Son Do (b) (4)	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:53:00

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Feb 2021 08:06:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 08:06:51
Data point term sent to Coder Coding entries removed.	System Nancy Tang (b) (4)	05 Feb 2021 23:29:40 05 Feb 2021 23:29:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 23:28:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 23:28:54
Data point term sent to Coder User entered 'advil'	System Benjamin Hull (b) (4) (b) (4)	01 Dec 2020 23:28:25 01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:54:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Subject has Medical history of Migraine headaches. This conmed was taken one time for their ongoing migraine headaches that is their baseline. Did not meet the AE reporting criteria.' (Site from DM).	Nancy Tang (b) (4)	05 Feb 2021 23:29:25
User entered 'MIGRAINE HEADACHE' reason for change: Data Entry Error	Nancy Tang (b) (4)	05 Feb 2021 23:29:18

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:51:13
User entered 'headache'	Benjamin Hull (b) (4) (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '200'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'mg (mg)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'once (ONCE)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Oral (ORAL)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '15 Sep 2020'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '0'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '15 Sep 2020'	Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given at Day 14 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:51:16
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given at Day 14 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' answered with 'Conmed was taken for Medical history of Migraines that subject has had since UNK2019. Please see medical history.' (Site from DM).	Nancy Tang (b) (4)	06 Apr 2021 17:39:11
Signature has been broken.	Nancy Tang (b) (4)	06 Apr 2021 17:38:30
User entered 'No (N)' reason for change: Data Entry Error	Nancy Tang (b) (4)	06 Apr 2021 17:38:30
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given at Day 14 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 00:19:24
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Benjamin Hull (b) (4)	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User entered empty.	System	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User entered empty.	System	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:18
User entered empty.	System	01 Dec 2020 23:27:33

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 19:06:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 19:06:56
Data point term sent to Coder	System	14 Jan 2021 19:05:52
Coding entries removed.	Benjamin Hull (b) (4)	14 Jan 2021 19:05:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 23:28:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 23:28:54
Data point term sent to Coder	System	01 Dec 2020 23:28:26
User entered 'flu shot'	Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'prophylaxis for flu' reason for change:	(b) (4)	
Data Entry Error	Benjamin Hull (b) (4)	14 Jan 2021 19:05:18
User entered 'flu'	(b) (4)	
	Benjamin Hull (b) (4)	01 Dec 2020 23:28:11
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '0.5' reason for change: Data Entry Error	(b) (4)	
	Benjamin Hull (b) (4)	14 Jan 2021 19:05:18
User entered '1'	(b) (4)	
	Benjamin Hull (b) (4)	01 Dec 2020 23:28:11
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Benjamin Hull (b) (4)	14 Jan 2021 19:05:18
User entered 'Other (OTHER)'	(b) (4)	
	Benjamin Hull (b) (4)	01 Dec 2020 23:28:11
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty; reason for change Data Entry Error	(b) (4)	
	Benjamin Hull (b) (4)	14 Jan 2021 19:05:18
User entered 'injection'	(b) (4)	
	Benjamin Hull (b) (4)	01 Dec 2020 23:28:11
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'once (ONCE)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Sep 2020'	Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '0'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '16 Sep 2020'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User entered empty.	System	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User entered empty.	System	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User entered empty.	System	01 Dec 2020 23:28:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 23:29:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 23:29:54
Data point term sent to Coder	System	01 Dec 2020 23:29:26
User entered 'advil'	Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:55:08
' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.'	Nancy Tang (b) (4)	05 Feb 2021 23:22:23
' answered with 'Solicited adverse reaction of HEADACHE happened within 7 day window of injection #2. HEADACHE did not meet the AE reporting criteria.' (Site from DM).		

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '200'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'mg (mg)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'twice daily (BID)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Oral (ORAL)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered empty.	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '4 Oct 2020'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '0'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered '6 Oct 2020'	Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'Yes (Y)'	Benjamin Hull (b) (4)	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User entered '2'	System	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User entered '1'	System	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:22
User entered '804 (804)'	System	01 Dec 2020 23:29:11

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 23:29:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 23:29:51
Data point term sent to Coder	System	22 Feb 2021 23:29:05
User entered 'Advil'	(b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered 'Fever'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered '200'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User entered empty.	System	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User entered empty.	System	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:24
User entered empty.	System	22 Feb 2021 23:28:09

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: OFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:22:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:22:42
Data point term sent to Coder	System	16 Mar 2021 22:34:24
User entered 'ofloxacin 0.3'	Colleen McLellan (b) (4) (b) (4)	16 Mar 2021 22:33:55

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'left cataract surgery'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '1'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'Other (OTHER)'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'drop'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'three times daily (TID)'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'Other (OTHER)'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'left eye (ophthalmic)'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '15 Mar 2021'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	16 Mar 2021 22:33:55
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Mar 2021 22:33:55

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 22:33:55

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 22:33:55

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 11:08:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:08:23
Data point term sent to Coder	System	02 Apr 2021 20:34:30
User entered 'iohexol (OMNIPAQUE 350)'	Colleen McLellan (b) (4) (b) (4)	02 Apr 2021 20:33:42

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'EPIGASTRIC PAIN'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '100'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'mL (mL)'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'once (ONCE)'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '28 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '28 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:33:42
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:33:42

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:33:42

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:33:42

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 10:04:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 10:04:52
Data point term sent to Coder	System	02 Apr 2021 20:34:30
User entered 'PROTONIX'	Colleen McLellan (b) (4) (b) (4)	02 Apr 2021 20:34:21

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'EPIGASTRIC PAIN'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '40'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'mg (mg)'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'once (ONCE)'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '29 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '29 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:34:21
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:34:21

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:34:21

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:34:21

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 20:36:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 20:36:48
Data point term sent to Coder User entered 'ZOSYN'	System Colleen McLellan (b) (4)	02 Apr 2021 20:35:32 02 Apr 2021 20:35:02

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'EPIGASTRIC PAIN'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '4500'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'mg (mg)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'once (ONCE)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '28 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '28 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:02
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:35:02

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:35:02

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:35:02

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 08:23:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 08:23:50
Data point term sent to Coder User entered 'AUGMENTIN'	System Colleen McLellan (b) (4)	02 Apr 2021 20:36:33 02 Apr 2021 20:35:52

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'EPIGASTRIC PAIN'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '875/125'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'mg (mg)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'twice daily (BID)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'Oral (ORAL)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '29 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Apr 2021 20:35:52
	(b) (4)	

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 20:35:52

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 20:35:52

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 20:35:52

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:50:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:50:46
Data point term sent to Coder	System	22 Apr 2021 22:44:35
User entered 'VALACYCLOVIR'	(b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'SHINGLES INFECTION'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '1000'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User entered '2'	System	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User entered '1'	System	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:29
User entered '804 (804)'	System	22 Apr 2021 22:44:17

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:14:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
Signature has been broken.	Colleen McLellan (b) (4)	16 Mar 2021 22:14:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	16 Mar 2021 22:14:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:40:19
User entered 'No (N)'	Son Do (b) (4)	17 Sep 2020 17:50:30

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:14:06

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:36
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered '15 Mar 2021'	Colleen McLellan (b) (4)	16 Mar 2021 22:15:14

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:14:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:36
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'left cataract surgery'	Colleen McLellan (b) (4)	16 Mar 2021 22:15:14

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:36
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered 'Medical History (MH)'	Colleen McLellan (b) (4)	16 Mar 2021 22:15:14

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:14:06

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:36
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:49
User entered empty.	(b) (4) Colleen McLellan (b) (4)	16 Mar 2021 22:15:14

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:14:06

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered '28 Mar 2021'	Colleen McLellan (b) (4)	02 Apr 2021 20:36:22
	(b) (4)	

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:14:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'ABDOMINAL CT'	Colleen McLellan (b) (4)	02 Apr 2021 20:36:22
	(b) (4)	

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:14:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Colleen McLellan (b) (4)	02 Apr 2021 20:36:22
	(b) (4)	

US3642081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:14:06

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:28:15
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Apr 2021 20:36:22
	(b) (4)	

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'USA-US109-2021-MRNA-1273-P301000012'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Yes (Y)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Yes (Y)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Stephen'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Spector'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'US'	System	05 Apr 2021 16:04:53

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 14:07:35
User entered '1'	System	05 Apr 2021 16:04:53

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'USA-US109-2021-MRNA-1273-P301000012'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Yes (Y)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Yes (Y)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Stephen'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Spector'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'US'	System	05 Apr 2021 16:04:53

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 14:07:35
User entered '1'	System	05 Apr 2021 16:04:53

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
User entered '05/Apr/2021 12:04'	(b) (4) System	05 Apr 2021 16:04:53

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:06

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 23:54:02
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'I'		05 Apr 2021 16:04:53

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'USA-US109-2021-MRNA-1273-P301000012'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Yes (Y)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Yes (Y)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'No (N)'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Stephen'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'Spector'	System	05 Apr 2021 16:03:44

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:04:57
User entered 'US'	System	05 Apr 2021 16:04:53

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 14:07:35
User entered '1'	System	05 Apr 2021 16:04:53

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:14:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:59
User entered '14/Apr/2021 10:07'	(b) (4) System	14 Apr 2021 14:07:35

US3642081

Folder: SAE USA-US109-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:14:06

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 18:01:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:07:35