

US3472013 (Prod: Penn Prevention - (CRS))

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:43:03

All time stamps listed in this document are displayed in GMT

US3472013

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

[Participant ID](#)

US3472013

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

US3472013

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: Screening

Form: Demographics

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
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

US3472013

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Date of Informed Consent (<i>dd MMM yyyy</i>)	02 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

US3472013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3472013

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Were any significant conditions reported?

Yes ☒

No ☐

US3472013

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Condition	MODERATE ASTHMA
Start date (dd MMM yyyy)	UN UNK 1968
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 1968
Start Year (derived)	1968
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3472013

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3472013

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Condition	SLEEP DISORDER
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3472013

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Condition	RENAL CELL CANCER
Start date (dd MMM yyyy)	07 AUG 2017
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)	14 AUG 2017
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2017
Start Year (derived)	2017
Stop Month and Year (derived)	AUG 2017
Stop Year (derived)	2017

US3472013

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Condition	MORBID OBESITY
Start date (dd MMM yyyy)	31 MAY 2006
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)	MAY 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3472013

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Condition	INTERSTITIAL TEARING OF THE LEFT GLUTEUS MEDIUS AND MINIMUS TENDONS
Start date (dd MMM yyyy)	18 OCT 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)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3472013

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Condition	MILD LEFT GREATER TROCHANTER BURSITIS
Start date (dd MMM yyyy)	18 OCT 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)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3472013

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Condition	DERMAL INJECTION, UNKNOWN TYPE, FOREHEAD
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3472013

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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>)	16:30 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 16:30
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	93.9 kg
BMI (<i>xxx.x</i>)	36.67052 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)	

US3472013

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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.

US3472013

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

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*) UN UNK 2010

Date of last menstruation unknown False

US3472013

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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	

US3472013

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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

What was the participant's randomization number? 145508

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 ☒

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Height	ND - Not Done
Weight	ND - Not Done

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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)	16:30 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 16:30
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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)	18:53 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 18:53
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3472013

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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.

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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) 18:09 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 18:09

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

US3472013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

17:45 (24 HR)

Collection date and time (derived)

02 SEP 2020 17:45

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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	17:48	02 SEP 2020 17:48
Nasopharyngeal Swab 2	No		

US3472013

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 18:38

PC Open Date & Time

02 SEP 2020 18:29

PC Close Date & Time

02 SEP 2020 20:59

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

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

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

PC Time Stamp 03 SEP 2020 09:30

PC Open Date & Time 02 SEP 2020 21:54

PC Close Date & Time 03 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False
PC Time Stamp	04 SEP 2020 09:35
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

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

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

PC Time Stamp 05 SEP 2020 08:14

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

06 SEP 2020 10:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

07 SEP 2020 09:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 09:16

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

97.6 °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

09 SEP 2020 07:49

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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 18:39

PC Open Date & Time

02 SEP 2020 18:29

PC Close Date & Time

02 SEP 2020 20:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

03 SEP 2020 09:31

PC Open Date & Time

02 SEP 2020 21:54

PC Close Date & Time

03 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

04 SEP 2020 09:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

05 SEP 2020 08:15

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

06 SEP 2020 10:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

07 SEP 2020 09:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

08 SEP 2020 09:16

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

09 SEP 2020 07:49

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 18:38
PC Open Date & Time	02 SEP 2020 18:29
PC Close Date & Time	02 SEP 2020 20:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 09:32
PC Open Date & Time	02 SEP 2020 21:54
PC Close Date & Time	03 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 09:37
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 08:15
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 10:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 09:10
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 09:16
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 07:50
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3472013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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)	28 SEP 2020
Time of assessment (00:00-23:59)	08:13 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:13
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	109 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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)	28 SEP 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:30
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3472013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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) 28 SEP 2020

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

Treatment Date and Time (derived) 28 SEP 2020 11:00

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

US3472013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

28 SEP 2020 08:25

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:27	28 SEP 2020 08:27
Nasopharyngeal Swab 2	No		

US3472013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 11:30

PC Open Date & Time

28 SEP 2020 11:20

PC Close Date & Time

28 SEP 2020 13:50

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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 97.4 °F

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

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

PC Time Stamp	29 SEP 2020 08:16
PC Open Date & Time	28 SEP 2020 14:45
PC Close Date & Time	29 SEP 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

30 SEP 2020 07:41

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 08:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

99.7 °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 07:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 OCT 2020 07:36

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

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.

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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 ☒

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 07:28

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 8

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

28 SEP 2020 11:31

PC Open Date & Time

28 SEP 2020 11:20

PC Close Date & Time

28 SEP 2020 13:50

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

29 SEP 2020 08:16

PC Open Date & Time

28 SEP 2020 14:45

PC Close Date & Time

29 SEP 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

30 SEP 2020 07:41

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

01 OCT 2020 08:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

02 OCT 2020 07:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

04 OCT 2020 07:37

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

05 OCT 2020 07:29

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 11:31
PC Open Date & Time	28 SEP 2020 11:20
PC Close Date & Time	28 SEP 2020 13:50

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 08:16
PC Open Date & Time	28 SEP 2020 14:45
PC Close Date & Time	29 SEP 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

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 ☒

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 07:42
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 08:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

101 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

	Yes <input type="checkbox"/>
PC Time stamp	02 OCT 2020 07:28
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

103 of 2054

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

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 ☒

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 07:37
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

107 of 2054

EAB) (1725)

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 07:29
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3472013

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:03

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	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3472013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 10:15
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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.

US3472013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 OCT 2020

Collection time (00:00-23:59)

10:35 (24 HR)

Collection date and time (derived)

29 OCT 2020 10:35

US3472013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

02 NOV 2020 03:31:00

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

09 NOV 2020 03:33:07

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

18 NOV 2020 12:00:24

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 12:00:57
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 07:16:20

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 12:16:18

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 08:21:53

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 14:17:32
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 02:51:32

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 07:55:34

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 00:01:35

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 07:41:07

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 03:58:16

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 05:03:28
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

21 FEB 2021 12:32:16

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 07:04:19

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 00:47:18

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 00:02:51
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 12:12:29

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 08:41:06

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 17:40:54

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 06:55:56

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

19 APR 2021 18:50:53

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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	26 APR 2021 17:59:25
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 00:58:49

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 <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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 271

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

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

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

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

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

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

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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="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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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="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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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°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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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°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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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="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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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="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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 <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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 <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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:43:03

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
Yes	No	02 MAR 2021 09:48:48

US3472013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:33

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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
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US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 18:58:06

Generated On: 09 Jun 2021 17:43:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:50 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 14:50
Temperature (<i>xxx.x</i>)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

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.

US3472013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 MAR 2021

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

16 MAR 2021 14:40

US3472013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:36:34

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 18:58:06

Generated On: 09 Jun 2021 17:43:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472013

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 18:58:06

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3472013

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:43:03

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"/>

US3472013

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:43:03

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3472013

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

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3472013

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

Form: Unblinding

Data signed: (b) (4) 02 May 2021 18:58:06

Generated On: 09 Jun 2021 17:43:03

Date of updated informed consent (dd MMM yyyy) 15 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3472013

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

15 JAN 2021 14:40

US3472013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	14:45
Collection Date and Time (derived)	15 JAN 2021 14:45

US3472013

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

AEID	USA-US122-2020-MRNA-1273-P30 1000001
Adverse event	ATELECTASIS
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)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

333 of 2054

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

POSTOPERATIVE ATELECTASIS
LEADING TO PROLONGED
HOSPITALIZATION DUE TO
HYPOXIA FOLLOWING
GASTRIC BAND SURGERY ON
21 SEP 2020. PARTICIPANT HAD
O2 SATURATION IN "HIGH 80S"
POSTOPERATIVELY, LEADING
TO 2 DAY HOSPITALIZATION
AND USE OF SUPPLEMENTAL
OXYGEN, WHICH SHE WAS
DISCHARGED WITH ON
9/23/2020. ATELECTASIS
CONFIRMED ON XRAY.
FOLLOWED UP WITH PCP ON
9/24/2020 AND OXYGEN
DISCONTINUED. NO ONGOING
SOB, O2 SATURATION 96% ON
ASSESSMENT.

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

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

AEID

Adverse event

ESOPHAGEAL SWELLING

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)

21 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

336 of 2054

EAB) (1725)

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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)	

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

AEID	
Adverse event	MENISCUS TORN, LEFT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

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

Yes ☒

No ☐

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

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication OMALIZUMAB

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 375

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

EVERY TWO WEEKS

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

PRODUCTION RELEASE (v12.003

341 of 2054

EAB) (1725)

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

343 of 2054

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	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 1996
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"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication CONCERTA

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 36

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

345 of 2054

EAB) (1725)

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	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 1998
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"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication SLEEP DISTURBANCE

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

347 of 2054

EAB) (1725)

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	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 2002	
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"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 1500

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)

349 of 2054

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	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)		02 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)		05 SEP 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"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POSTOPERATIVE PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

351 of 2054

EAB) (1725)

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	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)		21 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) 25 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"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication ACETAMINOPHEN-CODEINE
300-30MG

Prophylaxis Yes ☐
No ☒

Indication POSTOPERATIVE PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2054

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 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)		25 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"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR GERD
FOLLOWING GASTRIC BAND

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 2054

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 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)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POSTOPERATIVE PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

357 of 2054

EAB) (1725)

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 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) 04 OCT 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"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication POSTOPERATIVE
PROPHYLAXIS FOR DVT

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 ☐

PRODUCTION RELEASE (v12.003

359 of 2054

EAB) (1725)

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 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)		24 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"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication APIXABAN

Prophylaxis Yes ☒
No ☐

Indication POSTOPERATIVE
PROPHYLAXIS FOR DVT

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2054

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	Intraocular	<input type="radio"/>
	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

363 of 2054

EAB) (1725)

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Mar 2021 15:36:10

Generated On: 09 Jun 2021 17:43:03

	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 OCT 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 OCT 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"/>

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 SEP 2020	GASTRIC BAND SURGERY	Medical History	
01 OCT 2020	LEFT GLUTEUS MEDIUS TENDON REPAIR AND RECONSTRUCTION	Medical History	

US3472013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:43:03

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

US3472013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:43:03

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 ☐

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

SAEID	USA-US122-2020-MRNA-1273-P301000001
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	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

SAEID	USA-US122-2020-MRNA-1273-P301000001
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	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/SEP/2020 11:10
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

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

SAEID	USA-US122-2020-MRNA-1273-P301000001
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	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/OCT/2020 13:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Mar 2021 15:36:11

Generated On: 09 Jun 2021 17:43:03

SAEID	USA-US122-2020-MRNA-1273-P301000001
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	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/OCT/2020 10:05
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

US3472013 (Prod: Penn Prevention - (CRS))

US3472013

Form: Participant Creation

Generated On: 09 Jun 2021 17:43:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'US3472013'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 20:29:38

US3472013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:04

US3472013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 20:29:39

US3472013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Clinic (Clinic)'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:04

US3472013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'SCRN'	System	02 Sep 2020 22:17:04

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered (b) (6) 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 20:29:40

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '59'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'YEARS'	System	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '59'	System	02 Sep 2020 22:17:20

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Female (F)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'I'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:03

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:22:27

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Jie Ho (b) (4)	10 Nov 2020 20:48:21
User entered '2 Sep 2020'	Christopher Chianese	02 Sep 2020 22:17:20
	(b) (4)	

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Sep 2020'	System	02 Sep 2020 22:17:20

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2020'	System	02 Sep 2020 22:17:20

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Amendment 3 (3)'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:20

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:20

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:20

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:20

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:20

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 20:29:39

US3472013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'I'	System	02 Sep 2020 22:17:28

US3472013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:28

US3472013

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:43:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:56

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 03:46:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 03:46:32
Data point term sent to Coder	System	03 Sep 2020 03:46:18
User entered 'Moderate Asthma'	Jie Ho (b) (4)	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'un UNK 1968'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Jan 1968'	System	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '1968'	System	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	03 Sep 2020 03:45:33

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 03:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 03:50:37
Data point term sent to Coder	System	03 Sep 2020 03:49:18
User entered 'Depression'	Jie Ho (b) (4)	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'un UNK 1996'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Jan 1996'	System	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '1996'	System	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	03 Sep 2020 03:48:30

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Sleep disorders NEC, PT: Sleep disorder, LLT: Sleep disorder - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 03:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 03:50:37
Data point term sent to Coder	System	03 Sep 2020 03:50:19
User entered 'Sleep Disorder'	Jie Ho (b) (4)	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'un UNK 2002'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Jan 2002'	System	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2002'	System	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	03 Sep 2020 03:50:07

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cell carcinoma, LLT: Renal cell cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 03:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 03:52:39
Data point term sent to Coder	System	03 Sep 2020 03:51:19
User entered 'Renal Cell Cancer'	Jie Ho (b) (4)	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '07 Aug 2017'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
	(b) (4)	
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	03 Sep 2020 03:51:02
User entered '14 Aug 2017' reason for change: Data Entry Error	Jie Ho (b) (4)	03 Sep 2020 03:51:02
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	03 Sep 2020 03:50:54
User entered '04 Aug 2017'	Jie Ho (b) (4)	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Aug 2017'	System	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2017'	System	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Aug 2017'	System	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2017'	System	03 Sep 2020 03:50:54

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 18:29:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 18:29:24
Data point term sent to Coder	System	05 Oct 2020 18:29:05
User entered 'Morbid Obesity'	Jie Ho (b) (4)	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '31 May 2006' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 13:03:14
User entered empty.	Jie Ho (b) (4)	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:03:14
User entered '1'	Jie Ho (b) (4)	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'May 2006'	System	06 Oct 2020 13:03:14
User entered empty.	System	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2006'	System	06 Oct 2020 13:03:14
User entered empty.	System	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	05 Oct 2020 18:29:01

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Tendon rupture - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 08:11:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 08:11:53
User closed query 'Per DM CLR: INTERSTITIAL TEARING OF THE LEFT GLUTEUS MEDIUS AND MINIMUS TENDONS WITH ASSOCIATED MILD LEFT GREATER TROCHANTER BURSITIS is recorded. Please review if condition [INTERSTITIAL TEARING OF THE LEFT GLUTEUS MEDIUS AND MINIMUS TENDONS] and [MILD LEFT GREATER TROCHANTER BURSITIS] should be added as separate entry in the Medical History pages. Update if appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:27:32
Query 'Per DM CLR: INTERSTITIAL TEARING OF THE LEFT GLUTEUS MEDIUS AND MINIMUS TENDONS WITH ASSOCIATED MILD LEFT GREATER TROCHANTER BURSITIS is recorded. Please review if condition [INTERSTITIAL TEARING OF THE LEFT GLUTEUS MEDIUS AND MINIMUS TENDONS] and [MILD LEFT GREATER TROCHANTER BURSITIS] should be added as separate entry in the Medical History pages. Update if appropriate or provide clarification.' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	27 Oct 2020 02:48:37
Data point term sent to Coder	System	27 Oct 2020 02:47:59
User entered 'INTERSTITIAL TEARING OF THE LEFT GLUTEUS MEDIUS AND MINIMUS TENDONS' reason for change: Per Query Resolution	Jie Ho (b) (4)	27 Oct 2020 02:47:56

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: INTERSTITIAL TEARING OF THE LEFT GLUTEUS MEDIUS AND MINIMUS TENDONS WITH ASSOCIATED MILD LEFT GREATER TROCHANTER BURSITIS is recorded. Please review if condition [INTERSTITIAL TEARING OF THE LEFT GLUTEUS MEDIUS AND MINIMUS TENDONS] and [MILD LEFT GREATER TROCHANTER BURSITIS] should be added as separate entry in the Medical History pages. Update if appropriate or provide clarification.' (Site from DM). Data point term sent to Coder	(b) (4), (b) (6)	26 Oct 2020 09:28:50
	System	05 Oct 2020 18:47:04
User entered 'interstitial tearing of the left gluteus medius and minimus tendons with associated mild left greater trochanter bursitis'	(b) (4), (b) (6)	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '18 Oct 2018'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Oct 2018'	System	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2018'	System	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	05 Oct 2020 18:46:54

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Trochanteric bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 17:50:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 17:50:40
Data point term sent to Coder	System	27 Oct 2020 02:48:01
User entered 'MILD LEFT GREATER TROCHANTER BURSITIS'	Jie Ho (b) (4)	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '18 Oct 2018'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Oct 2018'	System	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2018'	System	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	System	27 Oct 2020 02:47:38

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 09:13:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 09:13:40
Data point term sent to Coder	System	17 Mar 2021 01:20:06
User entered 'Dermal injection, unknown type, forehead'	(b) (4), (b) (6)	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Jan 2015'	System	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2015'	System	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Jan 2015'	System	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '2015'	System	17 Mar 2021 01:19:12

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Jie Ho (b) (4)	10 Nov 2020 20:47:36
User entered '2 Sep 2020'	Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '16:30'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '02 Sep 2020 16:30'	System	10 Nov 2020 20:47:36
User entered '2 Sep 2020 16:30'	System	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '63' in DataPoint set to visible.	(b) (4) Jie Ho (b) (4) System	03 Sep 2020 03:26:08 02 Sep 2020 22:17:28

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '93.9' kg	(b) (4)	03 Sep 2020 03:26:08
DataPoint set to visible.	Jie Ho (b) (4)	02 Sep 2020 22:17:28
	System	

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '36.67052'	System	03 Sep 2020 03:26:08
DataPoint set to visible.	System	02 Sep 2020 22:17:28

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'kg/m2'	System	03 Sep 2020 03:26:08
DataPoint set to visible.	System	02 Sep 2020 22:17:28

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	03 Sep 2020 03:26:50
User entered 'Oral (Oral)'	Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'bpm'	System	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'breaths/min'	System	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'mmHg'	System	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'mmHg'	System	03 Sep 2020 03:26:08

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39

US3472013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39

US3472013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:53:22

US3472013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Jie Ho (b) (4)	10 Nov 2020 20:47:26
User entered '2 Sep 2020'	Jie Ho (b) (4)	03 Sep 2020 03:53:22

US3472013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Jie Ho (b) (4)	10 Nov 2020 20:47:17
User entered '2 Sep 2020'	Jie Ho (b) (4)	03 Sep 2020 04:25:56

US3472013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:25:56

US3472013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:03

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
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)	13 Oct 2020 08:10:19
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 'Per protocol only significant findings prior to signature of the informed consent are required to be included in the Medical History eCRF. This is not considered medically significant and thus not recorded.' (Site from DM).	Jie Ho (b) (4)	09 Oct 2020 18:23:18
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)	09 Oct 2020 05:18:17
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Jie Ho (b) (4)	03 Sep 2020 04:25:56

US3472013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:25:56

US3472013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:25:56

US3472013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:03

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:25:56

US3472013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'un UNK 2010'	Jie Ho (b) (4)	03 Sep 2020 04:25:56

US3472013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:03

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:25:56

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'I'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:27:00

US3472013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:54:10

US3472013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Jie Ho (b) (4)	10 Nov 2020 20:46:45
User entered '2 Sep 2020'	Jie Ho (b) (4)	03 Sep 2020 03:54:10

US3472013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	System	03 Sep 2020 03:54:12
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	Jie Ho (b) (4)	03 Sep 2020 03:54:12
User entered empty.	System	03 Sep 2020 03:54:10
	Jie Ho (b) (4)	03 Sep 2020 03:54:10

US3472013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'VISIT1'	System	03 Sep 2020 03:54:10

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 20:44:34

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '145508'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 20:44:34

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 20:44:34

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

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)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:53:57

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

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)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:53:57

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	Jie Ho (b) (4)	03 Sep 2020 03:53:57

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	Jie Ho (b) (4)	03 Sep 2020 03:53:57

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	Jie Ho (b) (4)	03 Sep 2020 03:53:57

US3472013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:03

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 08:31:47
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	07 Dec 2020 21:16:22
User entered 'No (N)'	Jie Ho (b) (4)	07 Dec 2020 21:16:17
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:49:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:01:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:01:37

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User accepted default value 'Pre-Dose (PREDOSE)'	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Jie Ho (b) (4)	10 Nov 2020 20:48:43
User entered '2 Sep 2020'	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '16:30'	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '02 Sep 2020 16:30'	System	10 Nov 2020 20:48:43
User entered '2 Sep 2020 16:30'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '36.5' C	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Oral (Oral)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '84'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'bpm'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '16'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'breaths/min'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '127'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '87'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered missing code ND - Not Done.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User accepted default value 'Post-Dose (POSTDOSE)'	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Jie Ho (b) (4)	10 Nov 2020 20:48:43
User entered '2 Sep 2020'	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '18:53'	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '02 Sep 2020 18:53'	System	10 Nov 2020 20:48:43
User entered '2 Sep 2020 18:53'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '36.9' C	Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Oral (Oral)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '68'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'bpm'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '16'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'breaths/min'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '145'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '90'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	03 Sep 2020 03:44:19

US3472013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	Jie Ho (b) (4)	03 Sep 2020 03:44:43

US3472013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:44:43

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

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)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
User entered '2 Sep 2020'	Jie Ho (b) (4)	10 Nov 2020 20:50:56
	Christopher Chianese	02 Sep 2020 22:17:57
	(b) (4)	

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '18:09'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '02 Sep 2020 18:09'	System	10 Nov 2020 20:50:56
User entered '2 Sep 2020 18:09'	System	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Christopher Chianese (b) (4)	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'ONCE'	System	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 22:17:57

US3472013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:23:11

US3472013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Jie Ho (b) (4)	10 Nov 2020 20:49:11
User entered '2 Sep 2020'	Jie Ho (b) (4)	03 Sep 2020 04:23:11

US3472013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '17:45'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:23:11

US3472013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '02 Sep 2020 17:45'	System	10 Nov 2020 20:49:11
User entered '2 Sep 2020 17:45'	System	03 Sep 2020 04:23:11

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:43:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Jie Ho (b) (4)	10 Nov 2020 20:50:10
User entered '2 Sep 2020'	Jie Ho (b) (4)	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jie Ho (b) (4)	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '17:48'	Jie Ho (b) (4)	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '02 Sep 2020 17:48'	System	10 Nov 2020 20:50:10
User entered '2 Sep 2020 17:48'	System	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User accepted default value 'Nasopharyngeal Swab 2 Jie Ho (NASAL2)'	(b) (4)	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	Jie Ho (b) (4)	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered empty.	System	03 Sep 2020 04:24:50

US3472013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	Jie Ho (b) (4)	03 Sep 2020 04:24:56

US3472013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'I'	System	03 Sep 2020 04:24:56

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:37:57', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '54a15d64-8b79-4452-98a7-0587b4700426' User entered 'Yes (Y)'	System	02 Sep 2020 22:38:19
	System	02 Sep 2020 22:38:19

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:06', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '54a15d64-8b79-4452-98a7-0587b4700426' User entered '98.5'	System	02 Sep 2020 22:38:19
	System	02 Sep 2020 22:38:19

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '54a15d64-8b79-4452-98a7-0587b4700426' User entered 'No (N)'	System	02 Sep 2020 22:38:19
	System	02 Sep 2020 22:38:19

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:17', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '54a15d64-8b79-4452-98a7-0587b4700426' User entered '02 Sep 2020 18:38'	System	02 Sep 2020 22:38:19
	System	02 Sep 2020 22:38:19

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 18:29'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 20:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:28:39', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '44f769af-8a43-442f-8d5e-1fbb2e4c473' User entered 'Yes (Y)'	System	03 Sep 2020 13:30:28
	System	03 Sep 2020 13:30:28

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:30:02', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '44f769af-8a43-442f-8d5e-1fbba2e4c473' User entered '97.8'	System	03 Sep 2020 13:30:28
	System	03 Sep 2020 13:30:28

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:30:08', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '44f769af-8a43-442f-8d5e-1fbba2e4c473'	System	03 Sep 2020 13:30:28
User entered 'Yes (Y)'	System	03 Sep 2020 13:30:28

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
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 'Medication details will be collected at the upcoming Safety Call Day 8 and reported.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 11:47:33
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.'	Jie Ho (b) (4)	04 Sep 2020 22:11:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:30:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '44f769af-8a43-442f-8d5e-1fbb2e4c473'	System	03 Sep 2020 13:30:28
User entered '1'	System	03 Sep 2020 13:30:28

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:30:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '44f769af-8a43-442f-8d5e-1fbb2e4c473' User entered '0'	System	03 Sep 2020 13:30:28
	System	03 Sep 2020 13:30:28

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:30:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '44f769af-8a43-442f-8d5e-1fbb2e4c473' User entered '03 Sep 2020 09:30'	System	03 Sep 2020 13:30:28
	System	03 Sep 2020 13:30:28

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 21:54'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 2'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:35:34', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86cb5cca-5607-48b6-a57f-34fa24d02b95' User entered 'Yes (Y)'	System	04 Sep 2020 13:35:56
	System	04 Sep 2020 13:35:56

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:35:42', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86cb5cca-5607-48b6-a57f-34fa24d02b95' User entered '97.3'	System	04 Sep 2020 13:35:56
	System	04 Sep 2020 13:35:56

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:35:46', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86cb5cca-5607-48b6-a57f-34fa24d02b95'	System	04 Sep 2020 13:35:56
User entered 'Yes (Y)'	System	04 Sep 2020 13:35:56

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
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 'Medication details will be collected at the upcoming Safety Call Day 8 and reported.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 11:47:38
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).	Jie Ho (b) (4)	04 Sep 2020 22:11:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:35:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86cb5cca-5607-48b6-a57f-34fa24d02b95'	System	04 Sep 2020 13:35:56
User entered '1'	System	04 Sep 2020 13:35:56

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:35:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86cb5cca-5607-48b6-a57f-34fa24d02b95' User entered '0'	System	04 Sep 2020 13:35:56
	System	04 Sep 2020 13:35:56

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:35:54', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86cb5cca-5607-48b6-a57f-34fa24d02b95' User entered '04 Sep 2020 09:35'	System	04 Sep 2020 13:35:56
	System	04 Sep 2020 13:35:56

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 3'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:14:17', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'eb389908-d5d0-461f-a9cf-bb98aa89ab87' User entered 'Yes (Y)'	System	05 Sep 2020 12:14:43
	System	05 Sep 2020 12:14:43

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:14:30', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'eb389908-d5d0-461f-a9cf-bb98aa89ab87' User entered '97.4'	System	05 Sep 2020 12:14:43
	System	05 Sep 2020 12:14:43

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:14:33', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'eb389908-d5d0-461f-a9cf-bb98aa89ab87'	System	05 Sep 2020 12:14:43
User entered 'Yes (Y)'	System	05 Sep 2020 12:14:43

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
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 'Medication details will be collected on Safety Call Day 8.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 11:47:43
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).	Jie Ho (b) (4)	05 Sep 2020 16:23:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:14:38', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'eb389908-d5d0-461f-a9cf-bb98aa89ab87'	System	05 Sep 2020 12:14:43
User entered '1'	System	05 Sep 2020 12:14:43

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:14:38', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'eb389908-d5d0-461f-a9cf-bb98aa89ab87' User entered '0'	System	05 Sep 2020 12:14:43
	System	05 Sep 2020 12:14:43

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:14:42', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'eb389908-d5d0-461f-a9cf-bb98aa89ab87' User entered '05 Sep 2020 08:14'	System	05 Sep 2020 12:14:43
	System	05 Sep 2020 12:14:43

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 4'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:44', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4bb1f955-73c7-45f0-b8b7-894db0106dcf' User entered 'Yes (Y)'	System	06 Sep 2020 14:02:29
	System	06 Sep 2020 14:02:29

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:02:06', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4bb1f955-73c7-45f0-b8b7-894db0106dcf' User entered '97.3'	System	06 Sep 2020 14:02:29
	System	06 Sep 2020 14:02:29

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:02:12', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4bb1f955-73c7-45f0-b8b7-894db0106dcf' User entered 'Yes (Y)'	System	06 Sep 2020 14:02:29
	System	06 Sep 2020 14:02:29

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
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 'Data will be collected at Safety Call Day 8. Thank you.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 08:52:26
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).	Jie Ho (b) (4)	08 Sep 2020 03:08:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:02:19', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4bb1f955-73c7-45f0-b8b7-894db0106dcf'	System	06 Sep 2020 14:02:29
User entered '1'	System	06 Sep 2020 14:02:29

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:02:19', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4bb1f955-73c7-45f0-b8b7-894db0106dcf' User entered '0'	System	06 Sep 2020 14:02:29
	System	06 Sep 2020 14:02:29

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:02:22', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4bb1f955-73c7-45f0-b8b7-894db0106dcf' User entered '06 Sep 2020 10:02'	System	06 Sep 2020 14:02:29
	System	06 Sep 2020 14:02:29

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 5'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:03', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8eb4b75d-314b-4a57-b5be-84eff8a041a5' User entered 'Yes (Y)'	System	07 Sep 2020 13:10:19
	System	07 Sep 2020 13:10:19

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8eb4b75d-314b-4a57-b5be-84eff8a041a5' User entered '97.2'	System	07 Sep 2020 13:10:19
	System	07 Sep 2020 13:10:19

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:14', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8eb4b75d-314b-4a57-b5be-84eff8a041a5' User entered 'No (N)'	System	07 Sep 2020 13:10:19
	System	07 Sep 2020 13:10:19

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:17', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8eb4b75d-314b-4a57-b5be-84eff8a041a5' User entered '07 Sep 2020 09:10'	System	07 Sep 2020 13:10:19
	System	07 Sep 2020 13:10:19

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 6'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:15:48', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '03670735-3ad4-45fc-83de-6ee8738f49bb' User entered 'Yes (Y)'	System	08 Sep 2020 13:16:04
	System	08 Sep 2020 13:16:04

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:15:55', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '03670735-3ad4-45fc-83de-6ee8738f49bb' User entered '97.3'	System	08 Sep 2020 13:16:04
	System	08 Sep 2020 13:16:04

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:15:58', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '03670735-3ad4-45fc-83de-6ee8738f49bb'	System	08 Sep 2020 13:16:04
User entered 'No (N)'	System	08 Sep 2020 13:16:04

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:01', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '03670735-3ad4-45fc-83de-6ee8738f49bb' User entered '08 Sep 2020 09:16'	System	08 Sep 2020 13:16:04
	System	08 Sep 2020 13:16:04

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 7'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '69ad2b37-ad56-442f-9537-11e7e1374241' User entered 'Yes (Y)'	System	09 Sep 2020 11:49:37
	System	09 Sep 2020 11:49:37

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '69ad2b37-ad56-442f-9537-11e7e1374241' User entered '97.6'	System	09 Sep 2020 11:49:37
	System	09 Sep 2020 11:49:37

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:31', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '69ad2b37-ad56-442f-9537-11e7e1374241'	System	09 Sep 2020 11:49:37
User entered 'No (N)'	System	09 Sep 2020 11:49:37

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:34', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '69ad2b37-ad56-442f-9537-11e7e1374241' User entered '09 Sep 2020 07:49'	System	09 Sep 2020 11:49:37
	System	09 Sep 2020 11:49:37

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:39:02', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '01c08ddb-2b17-48ab-b0b8-b66322523fea' User entered 'None (1)'	System	02 Sep 2020 22:39:33
	System	02 Sep 2020 22:39:33

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:39:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '01c08ddb-2b17-48ab-b0b8-b66322523fea' User entered 'No (N)'	System	02 Sep 2020 22:39:33
	System	02 Sep 2020 22:39:33

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:39:21', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '01c08ddb-2b17-48ab-b0b8-b66322523fea' User entered 'No (N)'	System	02 Sep 2020 22:39:33
	System	02 Sep 2020 22:39:33

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:39:27', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '01c08ddb-2b17-48ab-b0b8-b66322523fea' User entered 'None (1)'	System	02 Sep 2020 22:39:33
	System	02 Sep 2020 22:39:33

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:39:30', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '01c08ddb-2b17-48ab-b0b8-b66322523fea' User entered '02 Sep 2020 18:39'	System	02 Sep 2020 22:39:33
	System	02 Sep 2020 22:39:33

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 18:29'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 20:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:30:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '82102d43-6622-4fce-a261-42d24d263b27'	System	03 Sep 2020 13:31:24
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Sep 2020 13:31:24

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:30:54', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '82102d43-6622-4fce-a261-42d24d263b27' User entered 'No (N)'	System	03 Sep 2020 13:31:24
	System	03 Sep 2020 13:31:24

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:31:11', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '82102d43-6622-4fce-a261-42d24d263b27' User entered 'No (N)'	System	03 Sep 2020 13:31:24
	System	03 Sep 2020 13:31:24

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:31:16', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '82102d43-6622-4fce-a261-42d24d263b27'	System	03 Sep 2020 13:31:24
User entered 'None (1)'	System	03 Sep 2020 13:31:24

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:31:20', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '82102d43-6622-4fce-a261-42d24d263b27' User entered '03 Sep 2020 09:31'	System	03 Sep 2020 13:31:24
	System	03 Sep 2020 13:31:24

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 21:54'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 2'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:11', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '02de0200-162b-414d-bd53-41ee20ac830f'	System	04 Sep 2020 13:37:01
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 13:37:01

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:14', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '02de0200-162b-414d-bd53-41ee20ac830f' User entered 'No (N)'	System	04 Sep 2020 13:37:01
	System	04 Sep 2020 13:37:01

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:23', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '02de0200-162b-414d-bd53-41ee20ac830f' User entered 'No (N)'	System	04 Sep 2020 13:37:01
	System	04 Sep 2020 13:37:01

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:31', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '02de0200-162b-414d-bd53-41ee20ac830f'	System	04 Sep 2020 13:37:01
User entered 'None (1)'	System	04 Sep 2020 13:37:01

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:34', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '02de0200-162b-414d-bd53-41ee20ac830f' User entered '04 Sep 2020 09:36'	System	04 Sep 2020 13:37:01
	System	04 Sep 2020 13:37:01

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 3'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:14:58', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a7974110-ee7d-415b-8a19-df467e84cf9d'	System	05 Sep 2020 12:15:13
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	05 Sep 2020 12:15:13

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:01', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a7974110-ee7d-415b-8a19-df467e84cf9d' User entered 'No (N)'	System	05 Sep 2020 12:15:13
	System	05 Sep 2020 12:15:13

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:05', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a7974110-ee7d-415b-8a19-df467e84cf9d' User entered 'No (N)'	System	05 Sep 2020 12:15:13
	System	05 Sep 2020 12:15:13

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:08', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a7974110-ee7d-415b-8a19-df467e84cf9d' User entered 'None (1)'	System	05 Sep 2020 12:15:13
	System	05 Sep 2020 12:15:13

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:11', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a7974110-ee7d-415b-8a19-df467e84cf9d' User entered '05 Sep 2020 08:15'	System	05 Sep 2020 12:15:13
	System	05 Sep 2020 12:15:13

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 4'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:00:41', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c138f3c6-269a-49e4-a9b8-5e02581b1504'	System	06 Sep 2020 14:01:05
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	06 Sep 2020 14:01:05

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:00:45', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c138f3c6-269a-49e4-a9b8-5e02581b1504' User entered 'No (N)'	System	06 Sep 2020 14:01:05
	System	06 Sep 2020 14:01:05

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:00:52', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c138f3c6-269a-49e4-a9b8-5e02581b1504' User entered 'No (N)'	System	06 Sep 2020 14:01:05
	System	06 Sep 2020 14:01:05

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:00:57', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c138f3c6-269a-49e4-a9b8-5e02581b1504' User entered 'None (1)'	System	06 Sep 2020 14:01:05
	System	06 Sep 2020 14:01:05

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:01', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c138f3c6-269a-49e4-a9b8-5e02581b1504' User entered '06 Sep 2020 10:01'	System	06 Sep 2020 14:01:05
	System	06 Sep 2020 14:01:05

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 5'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:24', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '564c0cad-7ae2-4898-83ff-88f50b0bf6e6'	System	07 Sep 2020 13:10:39
User entered 'None (1)'	System	07 Sep 2020 13:10:39

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:27', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '564c0cad-7ae2-4898-83ff-88f50b0bf6e6' User entered 'No (N)'	System	07 Sep 2020 13:10:39
	System	07 Sep 2020 13:10:39

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:31', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '564c0cad-7ae2-4898-83ff-88f50b0bf6e6' User entered 'No (N)'	System	07 Sep 2020 13:10:39
	System	07 Sep 2020 13:10:39

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:33', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '564c0cad-7ae2-4898-83ff-88f50b0bf6e6' User entered 'None (1)'	System	07 Sep 2020 13:10:39
	System	07 Sep 2020 13:10:39

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:36', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '564c0cad-7ae2-4898-83ff-88f50b0bf6e6' User entered '07 Sep 2020 09:10'	System	07 Sep 2020 13:10:39
	System	07 Sep 2020 13:10:39

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 6'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:06', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b8d8ccf5-0311-4843-ad0c-282e48a60e78'	System	08 Sep 2020 13:16:22
User entered 'None (1)'	System	08 Sep 2020 13:16:22

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:09', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b8d8ccf5-0311-4843-ad0c-282e48a60e78'	System	08 Sep 2020 13:16:22
User entered 'No (N)'	System	08 Sep 2020 13:16:22

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:12', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b8d8ccf5-0311-4843-ad0c-282e48a60e78' User entered 'No (N)'	System	08 Sep 2020 13:16:22
	System	08 Sep 2020 13:16:22

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b8d8ccf5-0311-4843-ad0c-282e48a60e78' User entered 'None (1)'	System	08 Sep 2020 13:16:22
	System	08 Sep 2020 13:16:22

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:17', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b8d8ccf5-0311-4843-ad0c-282e48a60e78' User entered '08 Sep 2020 09:16'	System	08 Sep 2020 13:16:22
	System	08 Sep 2020 13:16:22

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 7'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:40', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2d9e1c0-6b96-4ce8-9049-5dfea8977668'	System	09 Sep 2020 11:49:59
User entered 'None (1)'	System	09 Sep 2020 11:49:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:45', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2d9e1c0-6b96-4ce8-9049-5dfea8977668'	System	09 Sep 2020 11:49:59
User entered 'No (N)'	System	09 Sep 2020 11:49:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2d9e1c0-6b96-4ce8-9049-5dfea8977668' User entered 'No (N)'	System	09 Sep 2020 11:49:59
	System	09 Sep 2020 11:49:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:54', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2d9e1c0-6b96-4ce8-9049-5dfea8977668'	System	09 Sep 2020 11:49:59
User entered 'None (1)'	System	09 Sep 2020 11:49:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:49:56', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2d9e1c0-6b96-4ce8-9049-5dfea8977668' User entered '09 Sep 2020 07:49'	System	09 Sep 2020 11:49:59
	System	09 Sep 2020 11:49:59

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:33', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fea3ade6-472b-4fcd-8bc4-23c14b63ae5f' User entered 'None (0)'	System	02 Sep 2020 22:38:59
	System	02 Sep 2020 22:38:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:36', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fea3ade6-472b-4fcd-8bc4-23c14b63ae5f' User entered 'None (0)'	System	02 Sep 2020 22:38:59
	System	02 Sep 2020 22:38:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:40', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fea3ade6-472b-4fcd-8bc4-23c14b63ae5f' User entered 'None (0)'	System	02 Sep 2020 22:38:59
	System	02 Sep 2020 22:38:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:43', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fea3ade6-472b-4fcd-8bc4-23c14b63ae5f' User entered 'None (0)'	System	02 Sep 2020 22:38:59
	System	02 Sep 2020 22:38:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:46', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fea3ade6-472b-4fcd-8bc4-23c14b63ae5f' User entered 'None (0)'	System	02 Sep 2020 22:38:59
	System	02 Sep 2020 22:38:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:48', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fea3ade6-472b-4fcd-8bc4-23c14b63ae5f' User entered 'None (0)'	System	02 Sep 2020 22:38:59
	System	02 Sep 2020 22:38:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:52', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fea3ade6-472b-4fcd-8bc4-23c14b63ae5f' User entered 'No (N)'	System	02 Sep 2020 22:38:59
	System	02 Sep 2020 22:38:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-02T18:38:56', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fea3ade6-472b-4fcd-8bc4-23c14b63ae5f' User entered '02 Sep 2020 18:38'	System	02 Sep 2020 22:38:59
	System	02 Sep 2020 22:38:59

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 18:29'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 20:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:31:30', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a60fa56d-3aa0-4e3e-b0a3-8c6b6d68c11e'	System	03 Sep 2020 13:32:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Sep 2020 13:32:37

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:31:43', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a60fa56d-3aa0-4e3e-b0a3-8c6b6d68c11e'	System	03 Sep 2020 13:32:37
User entered 'No interference with activity (1)'	System	03 Sep 2020 13:32:37

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:31:51', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a60fa56d-3aa0-4e3e-b0a3-8c6b6d68c11e'	System	03 Sep 2020 13:32:37
User entered 'No interference with activity (1)'	System	03 Sep 2020 13:32:37

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:31:56', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a60fa56d-3aa0-4e3e-b0a3-8c6b6d68c11e' User entered 'Some interference with activity (2)'	System	03 Sep 2020 13:32:37
	System	03 Sep 2020 13:32:37

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:32:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a60fa56d-3aa0-4e3e-b0a3-8c6b6d68c11e' User entered 'None (0)'	System	03 Sep 2020 13:32:37
	System	03 Sep 2020 13:32:37

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:32:02', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a60fa56d-3aa0-4e3e-b0a3-8c6b6d68c11e' User entered 'None (0)'	System	03 Sep 2020 13:32:37
	System	03 Sep 2020 13:32:37

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:32:06', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a60fa56d-3aa0-4e3e-b0a3-8c6b6d68c11e' User entered 'No (N)'	System	03 Sep 2020 13:32:37
	System	03 Sep 2020 13:32:37

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-03T09:32:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a60fa56d-3aa0-4e3e-b0a3-8c6b6d68c11e' User entered '03 Sep 2020 09:32'	System	03 Sep 2020 13:32:37
	System	03 Sep 2020 13:32:37

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Sep 2020 21:54'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 2'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:41', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e3d0b59d-b161-4225-b12c-277b6767ec73' User entered 'None (0)'	System	04 Sep 2020 13:37:13
	System	04 Sep 2020 13:37:13

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:46', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e3d0b59d-b161-4225-b12c-277b6767ec73'	System	04 Sep 2020 13:37:13
User entered 'No interference with activity (1)'	System	04 Sep 2020 13:37:13

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:51', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e3d0b59d-b161-4225-b12c-277b6767ec73'	System	04 Sep 2020 13:37:13
User entered 'Some interference with activity (2)'	System	04 Sep 2020 13:37:13

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:56', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e3d0b59d-b161-4225-b12c-277b6767ec73' User entered 'None (0)'	System	04 Sep 2020 13:37:13
	System	04 Sep 2020 13:37:13

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:36:59', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e3d0b59d-b161-4225-b12c-277b6767ec73' User entered 'None (0)'	System	04 Sep 2020 13:37:13
	System	04 Sep 2020 13:37:13

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:37:02', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e3d0b59d-b161-4225-b12c-277b6767ec73' User entered 'None (0)'	System	04 Sep 2020 13:37:13
	System	04 Sep 2020 13:37:13

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:37:05', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e3d0b59d-b161-4225-b12c-277b6767ec73' User entered 'No (N)'	System	04 Sep 2020 13:37:13
	System	04 Sep 2020 13:37:13

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-04T09:37:08', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e3d0b59d-b161-4225-b12c-277b6767ec73' User entered '04 Sep 2020 09:37'	System	04 Sep 2020 13:37:13
	System	04 Sep 2020 13:37:13

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 3'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:21', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2972030-6ddb-40cc-8236-ba8e79db7a4f' User entered 'None (0)'	System	05 Sep 2020 12:15:58
	System	05 Sep 2020 12:15:58

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:27', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2972030-6ddb-40cc-8236-ba8e79db7a4f'	System	05 Sep 2020 12:15:58
User entered 'No interference with activity (1)'	System	05 Sep 2020 12:15:58

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:34', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2972030-6ddb-40cc-8236-ba8e79db7a4f'	System	05 Sep 2020 12:15:58
User entered 'No interference with activity (1)'	System	05 Sep 2020 12:15:58

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:38', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2972030-6ddb-40cc-8236-ba8e79db7a4f' User entered 'None (0)'	System	05 Sep 2020 12:15:58
	System	05 Sep 2020 12:15:58

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:46', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2972030-6ddb-40cc-8236-ba8e79db7a4f' User entered 'None (0)'	System	05 Sep 2020 12:15:58
	System	05 Sep 2020 12:15:58

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:48', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2972030-6ddb-40cc-8236-ba8e79db7a4f' User entered 'None (0)'	System	05 Sep 2020 12:15:58
	System	05 Sep 2020 12:15:58

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:51', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2972030-6ddb-40cc-8236-ba8e79db7a4f' User entered 'No (N)'	System	05 Sep 2020 12:15:58
	System	05 Sep 2020 12:15:58

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-05T08:15:54', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'a2972030-6ddb-40cc-8236-ba8e79db7a4f' User entered '05 Sep 2020 08:15'	System	05 Sep 2020 12:15:58
	System	05 Sep 2020 12:15:58

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 4'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:08', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c85b54f6-2d46-41e6-8024-6b9b0efc3354' User entered 'None (0)'	System	06 Sep 2020 14:01:39
	System	06 Sep 2020 14:01:39

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:12', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c85b54f6-2d46-41e6-8024-6b9b0efc3354'	System	06 Sep 2020 14:01:39
User entered 'No interference with activity (1)'	System	06 Sep 2020 14:01:39

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:20', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c85b54f6-2d46-41e6-8024-6b9b0efc3354'	System	06 Sep 2020 14:01:39
User entered 'No interference with activity (1)'	System	06 Sep 2020 14:01:39

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:24', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c85b54f6-2d46-41e6-8024-6b9b0efc3354'	System	06 Sep 2020 14:01:39
User entered 'No interference with activity (1)'	System	06 Sep 2020 14:01:39

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:27', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c85b54f6-2d46-41e6-8024-6b9b0efc3354' User entered 'None (0)'	System	06 Sep 2020 14:01:39
	System	06 Sep 2020 14:01:39

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:30', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c85b54f6-2d46-41e6-8024-6b9b0efc3354' User entered 'None (0)'	System	06 Sep 2020 14:01:39
	System	06 Sep 2020 14:01:39

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:34', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c85b54f6-2d46-41e6-8024-6b9b0efc3354' User entered 'No (N)'	System	06 Sep 2020 14:01:39
	System	06 Sep 2020 14:01:39

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-06T10:01:37', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c85b54f6-2d46-41e6-8024-6b9b0efc3354' User entered '06 Sep 2020 10:01'	System	06 Sep 2020 14:01:39
	System	06 Sep 2020 14:01:39

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 5'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:40', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4924acee-1160-4ee2-9add-a76e02dbd4fe' User entered 'None (0)'	System	07 Sep 2020 13:11:01
	System	07 Sep 2020 13:11:01

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:43', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4924acee-1160-4ee2-9add-a76e02dbd4fe'	System	07 Sep 2020 13:11:01
User entered 'No interference with activity (1)'	System	07 Sep 2020 13:11:01

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:46', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4924acee-1160-4ee2-9add-a76e02dbd4fe' User entered 'None (0)'	System	07 Sep 2020 13:11:01
	System	07 Sep 2020 13:11:01

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:49', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4924acee-1160-4ee2-9add-a76e02dbd4fe' User entered 'None (0)'	System	07 Sep 2020 13:11:01
	System	07 Sep 2020 13:11:01

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:51', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4924acee-1160-4ee2-9add-a76e02dbd4fe' User entered 'None (0)'	System	07 Sep 2020 13:11:01
	System	07 Sep 2020 13:11:01

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:53', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4924acee-1160-4ee2-9add-a76e02dbd4fe' User entered 'None (0)'	System	07 Sep 2020 13:11:01
	System	07 Sep 2020 13:11:01

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:56', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4924acee-1160-4ee2-9add-a76e02dbd4fe' User entered 'No (N)'	System	07 Sep 2020 13:11:01
	System	07 Sep 2020 13:11:01

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-07T09:10:58', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4924acee-1160-4ee2-9add-a76e02dbd4fe' User entered '07 Sep 2020 09:10'	System	07 Sep 2020 13:11:01
	System	07 Sep 2020 13:11:01

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 6'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:22', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88118316-ce48-4e28-9f8a-fd8a42e5012e' User entered 'None (0)'	System	08 Sep 2020 13:16:41
	System	08 Sep 2020 13:16:41

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:24', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88118316-ce48-4e28-9f8a-fd8a42e5012e' User entered 'None (0)'	System	08 Sep 2020 13:16:41
	System	08 Sep 2020 13:16:41

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88118316-ce48-4e28-9f8a-fd8a42e5012e' User entered 'None (0)'	System	08 Sep 2020 13:16:41
	System	08 Sep 2020 13:16:41

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:28', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88118316-ce48-4e28-9f8a-fd8a42e5012e' User entered 'None (0)'	System	08 Sep 2020 13:16:41
	System	08 Sep 2020 13:16:41

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:31', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88118316-ce48-4e28-9f8a-fd8a42e5012e' User entered 'None (0)'	System	08 Sep 2020 13:16:41
	System	08 Sep 2020 13:16:41

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:33', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88118316-ce48-4e28-9f8a-fd8a42e5012e' User entered 'None (0)'	System	08 Sep 2020 13:16:41
	System	08 Sep 2020 13:16:41

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:36', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88118316-ce48-4e28-9f8a-fd8a42e5012e' User entered 'No (N)'	System	08 Sep 2020 13:16:41
	System	08 Sep 2020 13:16:41

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-08T09:16:39', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88118316-ce48-4e28-9f8a-fd8a42e5012e' User entered '08 Sep 2020 09:16'	System	08 Sep 2020 13:16:41
	System	08 Sep 2020 13:16:41

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 7'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:50:01', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '9409200a-055d-4831-abd9-3da80ee610ae' User entered 'None (0)'	System	09 Sep 2020 11:50:25
	System	09 Sep 2020 11:50:25

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:50:04', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '9409200a-055d-4831-abd9-3da80ee610ae' User entered 'None (0)'	System	09 Sep 2020 11:50:25
	System	09 Sep 2020 11:50:25

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:50:07', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '9409200a-055d-4831-abd9-3da80ee610ae' User entered 'None (0)'	System	09 Sep 2020 11:50:25
	System	09 Sep 2020 11:50:25

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:50:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '9409200a-055d-4831-abd9-3da80ee610ae' User entered 'None (0)'	System	09 Sep 2020 11:50:25
	System	09 Sep 2020 11:50:25

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:50:13', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '9409200a-055d-4831-abd9-3da80ee610ae' User entered 'None (0)'	System	09 Sep 2020 11:50:25
	System	09 Sep 2020 11:50:25

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:50:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '9409200a-055d-4831-abd9-3da80ee610ae' User entered 'None (0)'	System	09 Sep 2020 11:50:25
	System	09 Sep 2020 11:50:25

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:50:19', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '9409200a-055d-4831-abd9-3da80ee610ae' User entered 'No (N)'	System	09 Sep 2020 11:50:25
	System	09 Sep 2020 11:50:25

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-09T07:50:23', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '9409200a-055d-4831-abd9-3da80ee610ae' User entered '09 Sep 2020 07:50'	System	09 Sep 2020 11:50:25
	System	09 Sep 2020 11:50:25

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:17:57

US3472013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Christopher Chianese (b) (4)	09 Sep 2020 19:24:15

US3472013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '9 Sep 2020'	(b) (4) Christopher Chianese (b) (4)	09 Sep 2020 19:24:15

US3472013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christopher Chianese (b) (4)	09 Sep 2020 19:24:15

US3472013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Christopher Chianese (b) (4)	09 Sep 2020 19:24:15

US3472013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Christopher Chianese (b) (4)	09 Sep 2020 19:24:20

US3472013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'I'	System	09 Sep 2020 19:24:20

US3472013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:53:32

US3472013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:53:32

US3472013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:53:32

US3472013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:53:32

US3472013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:53:37

US3472013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'I'	System	16 Sep 2020 18:53:37

US3472013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:00:59

US3472013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:00:59

US3472013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:00:59

US3472013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:00:59

US3472013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:01:04

US3472013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'I'	System	28 Sep 2020 13:01:04

US3472013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:01:14

US3472013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:01:14

US3472013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[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 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:01:14

US3472013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'VISIT2'	System	28 Sep 2020 13:01:14

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User accepted default value 'Pre-Dose (PREDOSE)'	Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '28 Sep 2020'	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '08:13'	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '28 Sep 2020 08:13'	System	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '36.2' C	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Oral (Oral)'	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '109'	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'bpm'	System	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '18'	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'breaths/min'	System	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '120'	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '77'	(b) (4) Jie Ho (b) (4)	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	28 Sep 2020 14:31:28

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '11:30'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '28 Sep 2020 11:30'	System	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '37.2' C	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '98'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'bpm'	System	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '18'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'breaths/min'	System	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '119'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '75'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	29 Sep 2020 19:25:50

US3472013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:01:34

US3472013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:01:34

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

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)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '11:00'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '28 Sep 2020 11:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'ONCE'	System	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 15:18:24

US3472013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:02:04

US3472013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:02:04

US3472013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '08:25' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 13:02:11
User entered '08:13'	(b) (4), (b) (6)	28 Sep 2020 13:02:04

US3472013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '28 Sep 2020 08:25'	System	28 Sep 2020 13:02:11
User entered '28 Sep 2020 08:13'	System	28 Sep 2020 13:02:04

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:43:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '08:27'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '28 Sep 2020 08:27'	System	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered empty.	System	28 Sep 2020 13:02:32

US3472013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:20:19

US3472013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '1'	System	28 Sep 2020 15:20:19

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:30:20', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '2a5ffffef-5e5b-410e-bd0f-93948b791c38'	System	28 Sep 2020 15:30:43
User entered 'Yes (Y)'	System	28 Sep 2020 15:30:43

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:30:30', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '2a5ffffef-5e5b-410e-bd0f-93948b791c38' User entered '99.1'	System	28 Sep 2020 15:30:43
	System	28 Sep 2020 15:30:43

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:30:34', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '2a5ffffef-5e5b-410e-bd0f-93948b791c38'	System	28 Sep 2020 15:30:43
User entered 'No (N)'	System	28 Sep 2020 15:30:43

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:30:37', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '2a5ffffef-5e5b-410e-bd0f-93948b791c38'	System	28 Sep 2020 15:30:43
User entered '28 Sep 2020 11:30'	System	28 Sep 2020 15:30:43

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 11:20'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 13:50'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:15:54', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88344e26-cb38-4b72-baf9-e507f2e62866'	System	29 Sep 2020 12:16:14
User entered 'Yes (Y)'	System	29 Sep 2020 12:16:14

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:04', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88344e26-cb38-4b72-baf9-e507f2e62866' User entered '97.4'	System	29 Sep 2020 12:16:14
	System	29 Sep 2020 12:16:14

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:08', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88344e26-cb38-4b72-baf9-e507f2e62866'	System	29 Sep 2020 12:16:14
User entered 'No (N)'	System	29 Sep 2020 12:16:14

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:11', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '88344e26-cb38-4b72-baf9-e507f2e62866'	System	29 Sep 2020 12:16:14
User entered '29 Sep 2020 08:16'	System	29 Sep 2020 12:16:14

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 14:45'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 2'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:04', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e322302e-5c36-4f97-9421-63286733a369' User entered 'Yes (Y)'	System	30 Sep 2020 11:41:22
	System	30 Sep 2020 11:41:22

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:11', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e322302e-5c36-4f97-9421-63286733a369' User entered '97.2'	System	30 Sep 2020 11:41:22
	System	30 Sep 2020 11:41:22

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:16', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e322302e-5c36-4f97-9421-63286733a369' User entered 'No (N)'	System	30 Sep 2020 11:41:22
	System	30 Sep 2020 11:41:22

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:19', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e322302e-5c36-4f97-9421-63286733a369' User entered '30 Sep 2020 07:41'	System	30 Sep 2020 11:41:22
	System	30 Sep 2020 11:41:22

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 3'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:00:53', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '39f87178-f2a3-403e-90c4-52d40d839d48' User entered 'Yes (Y)'	System	01 Oct 2020 12:01:12
	System	01 Oct 2020 12:01:12

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:02', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '39f87178-f2a3-403e-90c4-52d40d839d48' User entered '98.4'	System	01 Oct 2020 12:01:12
	System	01 Oct 2020 12:01:12

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:08', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '39f87178-f2a3-403e-90c4-52d40d839d48'	System	01 Oct 2020 12:01:12
User entered 'No (N)'	System	01 Oct 2020 12:01:12

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '39f87178-f2a3-403e-90c4-52d40d839d48' User entered '01 Oct 2020 08:01'	System	01 Oct 2020 12:01:12
	System	01 Oct 2020 12:01:12

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 4'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:27:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4c6f954e-16ab-45cb-a9dc-a891c98f49f7' User entered 'Yes (Y)'	System	02 Oct 2020 11:28:07
	System	02 Oct 2020 11:28:07

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:27:35', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4c6f954e-16ab-45cb-a9dc-a891c98f49f7' User entered '99.7'	System	02 Oct 2020 11:28:07
	System	02 Oct 2020 11:28:07

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:27:57', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4c6f954e-16ab-45cb-a9dc-a891c98f49f7'	System	02 Oct 2020 11:28:07
User entered 'No (N)'	System	02 Oct 2020 11:28:07

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:02', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4c6f954e-16ab-45cb-a9dc-a891c98f49f7' User entered '02 Oct 2020 07:28'	System	02 Oct 2020 11:28:07
	System	02 Oct 2020 11:28:07

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 5'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 6'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:13', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8bb5b406-ad57-4a24-b275-f0807b525fa0' User entered 'Yes (Y)'	System	04 Oct 2020 11:36:34
	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:18', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8bb5b406-ad57-4a24-b275-f0807b525fa0' User entered '97.4'	System	04 Oct 2020 11:36:34
	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:25', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8bb5b406-ad57-4a24-b275-f0807b525fa0'	System	04 Oct 2020 11:36:34
User entered 'Yes (Y)'	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient reported she took oxycodone 5g to take postoperative pain.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 08:12:23
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).	(b) (4), (b) (6)	05 Oct 2020 20:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:30', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8bb5b406-ad57-4a24-b275-f0807b525fa0'	System	04 Oct 2020 11:36:34
User entered '1'	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:30', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8bb5b406-ad57-4a24-b275-f0807b525fa0' User entered '0'	System	04 Oct 2020 11:36:34
	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:32', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8bb5b406-ad57-4a24-b275-f0807b525fa0' User entered '04 Oct 2020 07:36'	System	04 Oct 2020 11:36:34
	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 7'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:28:42', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f918330b-496f-4d0a-a7e8-f4223ac30738' User entered 'No (N)'	System	05 Oct 2020 11:28:56
	System	05 Oct 2020 11:28:56

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:28:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f918330b-496f-4d0a-a7e8-f4223ac30738' User entered 'No (N)'	System	05 Oct 2020 11:28:56
	System	05 Oct 2020 11:28:56

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:28:54', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f918330b-496f-4d0a-a7e8-f4223ac30738' User entered '05 Oct 2020 07:28'	System	05 Oct 2020 11:28:56
	System	05 Oct 2020 11:28:56

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	04 Oct 2020 11:36:34
User entered 'Day 8'	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:30:46', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb334fda-4b0e-4050-a10c-941fed8fb252'	System	28 Sep 2020 15:31:06
User entered 'None (1)'	System	28 Sep 2020 15:31:06

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:30:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb334fda-4b0e-4050-a10c-941fed8fb252'	System	28 Sep 2020 15:31:06
User entered 'No (N)'	System	28 Sep 2020 15:31:06

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:30:55', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb334fda-4b0e-4050-a10c-941fed8fb252'	System	28 Sep 2020 15:31:06
User entered 'No (N)'	System	28 Sep 2020 15:31:06

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:30:59', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb334fda-4b0e-4050-a10c-941fed8fb252'	System	28 Sep 2020 15:31:06
User entered 'None (1)'	System	28 Sep 2020 15:31:06

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:02', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb334fda-4b0e-4050-a10c-941fed8fb252' User entered '28 Sep 2020 11:31'	System	28 Sep 2020 15:31:06
	System	28 Sep 2020 15:31:06

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 11:20'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 13:50'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:20', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '38b7cca0-0db2-45ac-93fd-5fdc9edccbb9'	System	29 Sep 2020 12:16:36
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 12:16:36

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:24', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '38b7cca0-0db2-45ac-93fd-5fdc9edccbb9' User entered 'No (N)'	System	29 Sep 2020 12:16:36
	System	29 Sep 2020 12:16:36

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:27', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '38b7cca0-0db2-45ac-93fd-5fdc9edccbb9' User entered 'No (N)'	System	29 Sep 2020 12:16:36
	System	29 Sep 2020 12:16:36

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:31', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '38b7cca0-0db2-45ac-93fd-5fdc9edccb9'	System	29 Sep 2020 12:16:36
User entered 'None (1)'	System	29 Sep 2020 12:16:36

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:33', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '38b7cca0-0db2-45ac-93fd-5fdc9edccbb9' User entered '29 Sep 2020 08:16'	System	29 Sep 2020 12:16:36
	System	29 Sep 2020 12:16:36

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 14:45'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 2'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:32', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fd67a16e-1e1e-4575-a48a-94730418f683'	System	30 Sep 2020 11:41:47
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 11:41:47

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:36', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fd67a16e-1e1e-4575-a48a-94730418f683'	System	30 Sep 2020 11:41:47
User entered 'No (N)'	System	30 Sep 2020 11:41:47

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:39', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fd67a16e-1e1e-4575-a48a-94730418f683' User entered 'No (N)'	System	30 Sep 2020 11:41:47
	System	30 Sep 2020 11:41:47

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:42', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fd67a16e-1e1e-4575-a48a-94730418f683' User entered 'None (1)'	System	30 Sep 2020 11:41:47
	System	30 Sep 2020 11:41:47

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:45', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'fd67a16e-1e1e-4575-a48a-94730418f683' User entered '30 Sep 2020 07:41'	System	30 Sep 2020 11:41:47
	System	30 Sep 2020 11:41:47

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 3'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:17', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb4e434c-827d-47fd-a008-52297f791a74'	System	01 Oct 2020 12:01:30
User entered 'None (1)'	System	01 Oct 2020 12:01:30

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:20', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb4e434c-827d-47fd-a008-52297f791a74' User entered 'No (N)'	System	01 Oct 2020 12:01:30
	System	01 Oct 2020 12:01:30

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:23', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb4e434c-827d-47fd-a008-52297f791a74' User entered 'No (N)'	System	01 Oct 2020 12:01:30
	System	01 Oct 2020 12:01:30

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb4e434c-827d-47fd-a008-52297f791a74'	System	01 Oct 2020 12:01:30
User entered 'None (1)'	System	01 Oct 2020 12:01:30

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:29', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'cb4e434c-827d-47fd-a008-52297f791a74' User entered '01 Oct 2020 08:01'	System	01 Oct 2020 12:01:30
	System	01 Oct 2020 12:01:30

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 4'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:07', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '93951ac4-20cb-4a33-b061-2a8ab2fb3e05'	System	02 Oct 2020 11:28:24
User entered 'None (1)'	System	02 Oct 2020 11:28:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:12', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '93951ac4-20cb-4a33-b061-2a8ab2fb3e05' User entered 'No (N)'	System	02 Oct 2020 11:28:24
	System	02 Oct 2020 11:28:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '93951ac4-20cb-4a33-b061-2a8ab2fb3e05' User entered 'No (N)'	System	02 Oct 2020 11:28:24
	System	02 Oct 2020 11:28:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:19', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '93951ac4-20cb-4a33-b061-2a8ab2fb3e05'	System	02 Oct 2020 11:28:24
User entered 'None (1)'	System	02 Oct 2020 11:28:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:22', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '93951ac4-20cb-4a33-b061-2a8ab2fb3e05' User entered '02 Oct 2020 07:28'	System	02 Oct 2020 11:28:24
	System	02 Oct 2020 11:28:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 5'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 6'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:38', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '0540b954-8b51-415a-8370-90575e4e81c4'	System	04 Oct 2020 11:37:08
User entered 'None (1)'	System	04 Oct 2020 11:37:08

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '0540b954-8b51-415a-8370-90575e4e81c4'	System	04 Oct 2020 11:37:08
User entered 'No (N)'	System	04 Oct 2020 11:37:08

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:53', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '0540b954-8b51-415a-8370-90575e4e81c4' User entered 'No (N)'	System	04 Oct 2020 11:37:08
	System	04 Oct 2020 11:37:08

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:36:56', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '0540b954-8b51-415a-8370-90575e4e81c4'	System	04 Oct 2020 11:37:08
User entered 'None (1)'	System	04 Oct 2020 11:37:08

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:01', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '0540b954-8b51-415a-8370-90575e4e81c4' User entered '04 Oct 2020 07:37'	System	04 Oct 2020 11:37:08
	System	04 Oct 2020 11:37:08

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 7'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:28:59', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8afcf6c8-d223-477a-85e8-46af92f2e52a' User entered 'None (1)'	System	05 Oct 2020 11:29:21
	System	05 Oct 2020 11:29:21

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:07', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8afcf6c8-d223-477a-85e8-46af92f2e52a' User entered 'No (N)'	System	05 Oct 2020 11:29:21
	System	05 Oct 2020 11:29:21

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8afcf6c8-d223-477a-85e8-46af92f2e52a' User entered 'No (N)'	System	05 Oct 2020 11:29:21
	System	05 Oct 2020 11:29:21

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:14', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8afcf6c8-d223-477a-85e8-46af92f2e52a' User entered 'None (1)'	System	05 Oct 2020 11:29:21
	System	05 Oct 2020 11:29:21

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:17', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '8afcf6c8-d223-477a-85e8-46af92f2e52a' User entered '05 Oct 2020 07:29'	System	05 Oct 2020 11:29:21
	System	05 Oct 2020 11:29:21

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:07', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '56ee0205-ed34-43b0-8f25-9a3e0b040207' User entered 'None (0)'	System	28 Sep 2020 15:32:39
	System	28 Sep 2020 15:32:39

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '56ee0205-ed34-43b0-8f25-9a3e0b040207' User entered 'None (0)'	System	28 Sep 2020 15:32:39
	System	28 Sep 2020 15:32:39

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:12', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '56ee0205-ed34-43b0-8f25-9a3e0b040207' User entered 'None (0)'	System	28 Sep 2020 15:32:39
	System	28 Sep 2020 15:32:39

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '56ee0205-ed34-43b0-8f25-9a3e0b040207' User entered 'None (0)'	System	28 Sep 2020 15:32:39
	System	28 Sep 2020 15:32:39

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:18', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '56ee0205-ed34-43b0-8f25-9a3e0b040207' User entered 'None (0)'	System	28 Sep 2020 15:32:39
	System	28 Sep 2020 15:32:39

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:20', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '56ee0205-ed34-43b0-8f25-9a3e0b040207' User entered 'None (0)'	System	28 Sep 2020 15:32:39
	System	28 Sep 2020 15:32:39

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:25', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '56ee0205-ed34-43b0-8f25-9a3e0b040207' User entered 'No (N)'	System	28 Sep 2020 15:32:39
	System	28 Sep 2020 15:32:39

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-28T11:31:28', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '56ee0205-ed34-43b0-8f25-9a3e0b040207' User entered '28 Sep 2020 11:31'	System	28 Sep 2020 15:32:39
	System	28 Sep 2020 15:32:39

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 11:20'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 13:50'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:38', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c81b8320-1dad-4547-a8b5-145b6c38ad52' User entered 'None (0)'	System	29 Sep 2020 12:17:03
	System	29 Sep 2020 12:17:03

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:41', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c81b8320-1dad-4547-a8b5-145b6c38ad52' User entered 'None (0)'	System	29 Sep 2020 12:17:03
	System	29 Sep 2020 12:17:03

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:44', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c81b8320-1dad-4547-a8b5-145b6c38ad52' User entered 'None (0)'	System	29 Sep 2020 12:17:03
	System	29 Sep 2020 12:17:03

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:47', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c81b8320-1dad-4547-a8b5-145b6c38ad52' User entered 'None (0)'	System	29 Sep 2020 12:17:03
	System	29 Sep 2020 12:17:03

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c81b8320-1dad-4547-a8b5-145b6c38ad52' User entered 'None (0)'	System	29 Sep 2020 12:17:03
	System	29 Sep 2020 12:17:03

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:53', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c81b8320-1dad-4547-a8b5-145b6c38ad52' User entered 'None (0)'	System	29 Sep 2020 12:17:03
	System	29 Sep 2020 12:17:03

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:56', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c81b8320-1dad-4547-a8b5-145b6c38ad52' User entered 'No (N)'	System	29 Sep 2020 12:17:03
	System	29 Sep 2020 12:17:03

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-29T08:16:59', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'c81b8320-1dad-4547-a8b5-145b6c38ad52' User entered '29 Sep 2020 08:16'	System	29 Sep 2020 12:17:03
	System	29 Sep 2020 12:17:03

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '28 Sep 2020 14:45'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 2'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '46967973-28aa-49a0-a2c8-7b3026b98f9a' User entered 'None (0)'	System	30 Sep 2020 11:42:11
	System	30 Sep 2020 11:42:11

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:53', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '46967973-28aa-49a0-a2c8-7b3026b98f9a' User entered 'None (0)'	System	30 Sep 2020 11:42:11
	System	30 Sep 2020 11:42:11

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:56', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '46967973-28aa-49a0-a2c8-7b3026b98f9a' User entered 'None (0)'	System	30 Sep 2020 11:42:11
	System	30 Sep 2020 11:42:11

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:41:59', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '46967973-28aa-49a0-a2c8-7b3026b98f9a' User entered 'None (0)'	System	30 Sep 2020 11:42:11
	System	30 Sep 2020 11:42:11

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:42:01', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '46967973-28aa-49a0-a2c8-7b3026b98f9a' User entered 'None (0)'	System	30 Sep 2020 11:42:11
	System	30 Sep 2020 11:42:11

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:42:04', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '46967973-28aa-49a0-a2c8-7b3026b98f9a' User entered 'None (0)'	System	30 Sep 2020 11:42:11
	System	30 Sep 2020 11:42:11

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:42:07', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '46967973-28aa-49a0-a2c8-7b3026b98f9a' User entered 'No (N)'	System	30 Sep 2020 11:42:11
	System	30 Sep 2020 11:42:11

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-09-30T07:42:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '46967973-28aa-49a0-a2c8-7b3026b98f9a' User entered '30 Sep 2020 07:42'	System	30 Sep 2020 11:42:11
	System	30 Sep 2020 11:42:11

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 3'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:33', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e9e98caf-b6a5-4835-934b-5a87000985a8' User entered 'None (0)'	System	01 Oct 2020 12:01:52
	System	01 Oct 2020 12:01:52

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:36', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e9e98caf-b6a5-4835-934b-5a87000985a8' User entered 'None (0)'	System	01 Oct 2020 12:01:52
	System	01 Oct 2020 12:01:52

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:38', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e9e98caf-b6a5-4835-934b-5a87000985a8' User entered 'None (0)'	System	01 Oct 2020 12:01:52
	System	01 Oct 2020 12:01:52

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:41', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e9e98caf-b6a5-4835-934b-5a87000985a8' User entered 'None (0)'	System	01 Oct 2020 12:01:52
	System	01 Oct 2020 12:01:52

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:43', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e9e98caf-b6a5-4835-934b-5a87000985a8' User entered 'None (0)'	System	01 Oct 2020 12:01:52
	System	01 Oct 2020 12:01:52

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:45', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e9e98caf-b6a5-4835-934b-5a87000985a8' User entered 'None (0)'	System	01 Oct 2020 12:01:52
	System	01 Oct 2020 12:01:52

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:48', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e9e98caf-b6a5-4835-934b-5a87000985a8' User entered 'No (N)'	System	01 Oct 2020 12:01:52
	System	01 Oct 2020 12:01:52

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-01T08:01:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'e9e98caf-b6a5-4835-934b-5a87000985a8' User entered '01 Oct 2020 08:01'	System	01 Oct 2020 12:01:52
	System	01 Oct 2020 12:01:52

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 4'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:28', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '696246a7-7c91-47fa-b71b-48c468fe93d7' User entered 'None (0)'	System	02 Oct 2020 11:28:59
	System	02 Oct 2020 11:28:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:31', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '696246a7-7c91-47fa-b71b-48c468fe93d7' User entered 'None (0)'	System	02 Oct 2020 11:28:59
	System	02 Oct 2020 11:28:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:33', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '696246a7-7c91-47fa-b71b-48c468fe93d7' User entered 'None (0)'	System	02 Oct 2020 11:28:59
	System	02 Oct 2020 11:28:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:36', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '696246a7-7c91-47fa-b71b-48c468fe93d7' User entered 'None (0)'	System	02 Oct 2020 11:28:59
	System	02 Oct 2020 11:28:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:38', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '696246a7-7c91-47fa-b71b-48c468fe93d7' User entered 'None (0)'	System	02 Oct 2020 11:28:59
	System	02 Oct 2020 11:28:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:41', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '696246a7-7c91-47fa-b71b-48c468fe93d7' User entered 'None (0)'	System	02 Oct 2020 11:28:59
	System	02 Oct 2020 11:28:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:52', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '696246a7-7c91-47fa-b71b-48c468fe93d7' User entered 'Yes (Y)'	System	02 Oct 2020 11:28:59
	System	02 Oct 2020 11:28:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-02T07:28:55', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '696246a7-7c91-47fa-b71b-48c468fe93d7' User entered '02 Oct 2020 07:28'	System	02 Oct 2020 11:28:59
	System	02 Oct 2020 11:28:59

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 5'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 6'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b107a927-35e0-45b6-a471-0204371a2f11' User entered 'None (0)'	System	04 Oct 2020 11:37:31
	System	04 Oct 2020 11:37:31

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:14', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b107a927-35e0-45b6-a471-0204371a2f11' User entered 'None (0)'	System	04 Oct 2020 11:37:31
	System	04 Oct 2020 11:37:31

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:17', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b107a927-35e0-45b6-a471-0204371a2f11' User entered 'None (0)'	System	04 Oct 2020 11:37:31
	System	04 Oct 2020 11:37:31

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:19', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b107a927-35e0-45b6-a471-0204371a2f11' User entered 'None (0)'	System	04 Oct 2020 11:37:31
	System	04 Oct 2020 11:37:31

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:21', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b107a927-35e0-45b6-a471-0204371a2f11' User entered 'None (0)'	System	04 Oct 2020 11:37:31
	System	04 Oct 2020 11:37:31

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:24', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b107a927-35e0-45b6-a471-0204371a2f11' User entered 'None (0)'	System	04 Oct 2020 11:37:31
	System	04 Oct 2020 11:37:31

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b107a927-35e0-45b6-a471-0204371a2f11' User entered 'No (N)'	System	04 Oct 2020 11:37:31
	System	04 Oct 2020 11:37:31

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-04T07:37:28', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'b107a927-35e0-45b6-a471-0204371a2f11' User entered '04 Oct 2020 07:37'	System	04 Oct 2020 11:37:31
	System	04 Oct 2020 11:37:31

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	28 Sep 2020 15:18:24
User entered 'Day 7'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:22', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4facb547-8af2-4f45-9aba-94fbe8f77012' User entered 'None (0)'	System	05 Oct 2020 11:29:48
	System	05 Oct 2020 11:29:48

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4facb547-8af2-4f45-9aba-94fbe8f77012' User entered 'None (0)'	System	05 Oct 2020 11:29:48
	System	05 Oct 2020 11:29:48

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:29', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4facb547-8af2-4f45-9aba-94fbe8f77012' User entered 'None (0)'	System	05 Oct 2020 11:29:48
	System	05 Oct 2020 11:29:48

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:32', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4facb547-8af2-4f45-9aba-94fbe8f77012' User entered 'None (0)'	System	05 Oct 2020 11:29:48
	System	05 Oct 2020 11:29:48

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:35', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4facb547-8af2-4f45-9aba-94fbe8f77012' User entered 'None (0)'	System	05 Oct 2020 11:29:48
	System	05 Oct 2020 11:29:48

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:37', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4facb547-8af2-4f45-9aba-94fbe8f77012' User entered 'None (0)'	System	05 Oct 2020 11:29:48
	System	05 Oct 2020 11:29:48

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:40', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4facb547-8af2-4f45-9aba-94fbe8f77012'	System	05 Oct 2020 11:29:48
User entered 'No (N)'	System	05 Oct 2020 11:29:48

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-10-05T07:29:43', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4facb547-8af2-4f45-9aba-94fbe8f77012' User entered '05 Oct 2020 07:29'	System	05 Oct 2020 11:29:48
	System	05 Oct 2020 11:29:48

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:18:24

US3472013

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	04 Oct 2020 11:36:34
User entered 'Day 8'	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05

US3472013

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 11:36:34

US3472013

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 11:36:34

US3472013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:43:07

US3472013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:43:07

US3472013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:43:07

US3472013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:43:07

US3472013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:43:12

US3472013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'I'	System	05 Oct 2020 18:43:12

US3472013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:20:56

US3472013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:20:56

US3472013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:20:56

US3472013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:20:56

US3472013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:21:01

US3472013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'I'	System	12 Oct 2020 16:21:01

US3472013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:40:41

US3472013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '20 Oct 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:01:53
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:40:41

US3472013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	20 Oct 2020 21:01:53
reason for change: New Information	(b) (4), (b) (6)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	19 Oct 2020 15:40:41

US3472013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty; reason for change New Information	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:01:53
User entered 'voicemail box was full; could not leave a message'	(b) (4), (b) (6)	19 Oct 2020 15:40:41

US3472013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:01:56

US3472013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'I'	System	20 Oct 2020 21:01:56

US3472013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:09:52

US3472013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:09:52

US3472013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[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 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:09:52

US3472013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'VISIT3'	System	29 Oct 2020 22:09:52

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '10:15'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '29 Oct 2020 10:15'	System	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '79'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'bpm'	System	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'breaths/min'	System	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '114'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '75'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'mmHg'	System	29 Oct 2020 22:10:54

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14

US3472013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14

US3472013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:11:05

US3472013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:11:05

US3472013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:11:21

US3472013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:11:21

US3472013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '10:35'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:11:21

US3472013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '29 Oct 2020 10:35'	System	29 Oct 2020 22:11:21

US3472013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:11:27

US3472013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered '1'	System	29 Oct 2020 22:11:27

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 64'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-02T03:30:49', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd156f5b8-a604-4ef6-bd99-8bdbb58935e0' User entered 'No (N)'	System	02 Nov 2020 08:31:01
	System	02 Nov 2020 08:31:01

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-02T03:30:54', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd156f5b8-a604-4ef6-bd99-8bdbb58935e0' User entered 'No (N)'	System	02 Nov 2020 08:31:01
	System	02 Nov 2020 08:31:01

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-02T03:31:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd156f5b8-a604-4ef6-bd99-8bdbb58935e0' User entered '02 Nov 2020 03:31:00'	System	02 Nov 2020 08:31:01
	System	02 Nov 2020 08:31:01

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 71'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-09T03:32:57', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd3ef6b7e-1de8-4be4-a1e3-5df5156b73b0'	System	09 Nov 2020 08:33:09
User entered 'No (N)'	System	09 Nov 2020 08:33:09

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-09T03:33:03', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd3ef6b7e-1de8-4be4-a1e3-5df5156b73b0'	System	09 Nov 2020 08:33:09
User entered 'No (N)'	System	09 Nov 2020 08:33:09

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-09T03:33:07', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd3ef6b7e-1de8-4be4-a1e3-5df5156b73b0' User entered '09 Nov 2020 03:33:07'	System	09 Nov 2020 08:33:09
	System	09 Nov 2020 08:33:09

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered 'Day 78'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-18T12:00:16', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f991f9b4-5c0f-49f1-a314-a6574cb70c71'	System	18 Nov 2020 17:00:31
User entered 'No (N)'	System	18 Nov 2020 17:00:31

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-18T12:00:21', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f991f9b4-5c0f-49f1-a314-a6574cb70c71'	System	18 Nov 2020 17:00:31
User entered 'No (N)'	System	18 Nov 2020 17:00:31

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-11-18T12:00:24', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f991f9b4-5c0f-49f1-a314-a6574cb70c71' User entered '18 Nov 2020 12:00:24'	System	18 Nov 2020 17:00:31
	System	18 Nov 2020 17:00:31

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 22:17:57

US3472013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:18:05
Data entry locked.	System	02 Sep 2020 22:17:57
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 22:17:57

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-06T12:00:49', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '3c34fdc8-d158-4296-9bd7-521d4feaf27a' User entered 'No (N)'	System	06 Dec 2020 17:01:14
	System	06 Dec 2020 17:01:14

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-06T12:00:53', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '3c34fdc8-d158-4296-9bd7-521d4feaf27a' User entered 'No (N)'	System	06 Dec 2020 17:01:14
	System	06 Dec 2020 17:01:14

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-06T12:00:57', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '3c34fdc8-d158-4296-9bd7-521d4feaf27a' User entered '06 Dec 2020 12:00:57'	System	06 Dec 2020 17:01:14
	System	06 Dec 2020 17:01:14

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-11T07:16:13', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f52ed895-130d-4c42-a85f-a27a3415907d' User entered 'No (N)'	System	11 Dec 2020 12:16:23
	System	11 Dec 2020 12:16:23

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-11T07:16:17', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f52ed895-130d-4c42-a85f-a27a3415907d' User entered 'No (N)'	System	11 Dec 2020 12:16:23
	System	11 Dec 2020 12:16:23

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-11T07:16:20', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'f52ed895-130d-4c42-a85f-a27a3415907d' User entered '11 Dec 2020 07:16:20'	System	11 Dec 2020 12:16:23
	System	11 Dec 2020 12:16:23

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-20T12:16:11', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1de6e696-a609-41bb-859f-6c7da0f33dcb' User entered 'No (N)'	System	20 Dec 2020 17:16:27
	System	20 Dec 2020 17:16:27

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-20T12:16:15', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1de6e696-a609-41bb-859f-6c7da0f33dcb' User entered 'No (N)'	System	20 Dec 2020 17:16:27
	System	20 Dec 2020 17:16:27

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-20T12:16:18', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1de6e696-a609-41bb-859f-6c7da0f33dcb' User entered '20 Dec 2020 12:16:18'	System	20 Dec 2020 17:16:27
	System	20 Dec 2020 17:16:27

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-25T08:21:46', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '956363d6-a283-4409-b5f4-4c91e444ba6f' User entered 'No (N)'	System	25 Dec 2020 13:21:55
	System	25 Dec 2020 13:21:55

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-25T08:21:50', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '956363d6-a283-4409-b5f4-4c91e444ba6f' User entered 'No (N)'	System	25 Dec 2020 13:21:55
	System	25 Dec 2020 13:21:55

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2020-12-25T08:21:53', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '956363d6-a283-4409-b5f4-4c91e444ba6f' User entered '25 Dec 2020 08:21:53'	System	25 Dec 2020 13:21:55
	System	25 Dec 2020 13:21:55

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-01T14:17:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '09761ed5-2fd2-4942-a642-7a3fb4d388bc' User entered 'No (N)'	System	01 Jan 2021 19:17:34
	System	01 Jan 2021 19:17:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-01T14:17:29', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '09761ed5-2fd2-4942-a642-7a3fb4d388bc' User entered 'No (N)'	System	01 Jan 2021 19:17:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-01T14:17:32', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '09761ed5-2fd2-4942-a642-7a3fb4d388bc' User entered '01 Jan 2021 14:17:32'	System	01 Jan 2021 19:17:34
	System	01 Jan 2021 19:17:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-08T02:51:24', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '7a92b89a-4b4c-49cf-847c-5eccdaed8b17'	System	08 Jan 2021 07:51:34
User entered 'No (N)'	System	08 Jan 2021 07:51:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-08T02:51:28', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '7a92b89a-4b4c-49cf-847c-5eccdaed8b17'	System	08 Jan 2021 07:51:34
User entered 'No (N)'	System	08 Jan 2021 07:51:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-08T02:51:32', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '7a92b89a-4b4c-49cf-847c-5eccdaed8b17' User entered '08 Jan 2021 02:51:32'	System	08 Jan 2021 07:51:34
	System	08 Jan 2021 07:51:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-15T07:55:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1107b554-0b68-4e5c-895d-83f4b3082d68'	System	15 Jan 2021 12:55:36
User entered 'No (N)'	System	15 Jan 2021 12:55:36

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-15T07:55:31', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1107b554-0b68-4e5c-895d-83f4b3082d68'	System	15 Jan 2021 12:55:36
User entered 'No (N)'	System	15 Jan 2021 12:55:36

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-15T07:55:34', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1107b554-0b68-4e5c-895d-83f4b3082d68' User entered '15 Jan 2021 07:55:34'	System	15 Jan 2021 12:55:36
	System	15 Jan 2021 12:55:36

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-22T00:01:26', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4f011964-ce49-47fe-823f-9951e79d8793'	System	22 Jan 2021 05:01:45
User entered 'No (N)'	System	22 Jan 2021 05:01:45

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-22T00:01:31', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4f011964-ce49-47fe-823f-9951e79d8793'	System	22 Jan 2021 05:01:45
User entered 'No (N)'	System	22 Jan 2021 05:01:45

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-01-22T00:01:35', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '4f011964-ce49-47fe-823f-9951e79d8793' User entered '22 Jan 2021 00:01:35'	System	22 Jan 2021 05:01:45
	System	22 Jan 2021 05:01:45

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-01T07:40:59', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '533278bf-2265-4555-965d-551f2dfc87eb' User entered 'No (N)'	System	01 Feb 2021 12:41:09
	System	01 Feb 2021 12:41:09

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-01T07:41:03', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '533278bf-2265-4555-965d-551f2dfc87eb' User entered 'No (N)'	System	01 Feb 2021 12:41:09
	System	01 Feb 2021 12:41:09

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-01T07:41:07', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '533278bf-2265-4555-965d-551f2dfc87eb' User entered '01 Feb 2021 07:41:07'	System	01 Feb 2021 12:41:09
	System	01 Feb 2021 12:41:09

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-05T03:58:07', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '17c15114-a4c8-416c-9322-6b62e21578c9' User entered 'No (N)'	System	05 Feb 2021 08:58:17
	System	05 Feb 2021 08:58:17

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-05T03:58:10', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '17c15114-a4c8-416c-9322-6b62e21578c9'	System	05 Feb 2021 08:58:17
User entered 'No (N)'	System	05 Feb 2021 08:58:17

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-05T03:58:16', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '17c15114-a4c8-416c-9322-6b62e21578c9' User entered '05 Feb 2021 03:58:16'	System	05 Feb 2021 08:58:17
	System	05 Feb 2021 08:58:17

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-12T05:03:18', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1face068-f8b5-488b-9780-3a1afde9ef3d' User entered 'No (N)'	System	12 Feb 2021 10:03:34
	System	12 Feb 2021 10:03:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-12T05:03:24', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1face068-f8b5-488b-9780-3a1afde9ef3d' User entered 'No (N)'	System	12 Feb 2021 10:03:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-12T05:03:28', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1face068-f8b5-488b-9780-3a1afde9ef3d' User entered '12 Feb 2021 05:03:28'	System	12 Feb 2021 10:03:34
	System	12 Feb 2021 10:03:34

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-21T12:32:08', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '474a212d-a357-4f05-a287-65d188edf0bf' User entered 'No (N)'	System	21 Feb 2021 17:32:18
	System	21 Feb 2021 17:32:18

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-21T12:32:11', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '474a212d-a357-4f05-a287-65d188edf0bf' User entered 'No (N)'	System	21 Feb 2021 17:32:18

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-21T12:32:16', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '474a212d-a357-4f05-a287-65d188edf0bf' User entered '21 Feb 2021 12:32:16'	System	21 Feb 2021 17:32:18
	System	21 Feb 2021 17:32:18

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-26T02:04:11-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '36771260-1a01-4181-b164-28fbdfcf08c6'	System	02 Mar 2021 14:48:36
User entered 'No (N)'	System	02 Mar 2021 14:48:36

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-26T02:04:15-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '36771260-1a01-4181-b164-28fbdfcf08c6'	System	02 Mar 2021 14:48:36
User entered 'No (N)'	System	02 Mar 2021 14:48:36

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-02-26T02:04:19-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '36771260-1a01-4181-b164-28fbdfcf08c6'	System	02 Mar 2021 14:48:36
User entered '26 Feb 2021 07:04:19'	System	02 Mar 2021 14:48:36

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-05T00:47:08-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd3431d7d-0933-4a88-86f6-78267319cb71'	System	05 Mar 2021 05:47:20
User entered 'No (N)'	System	05 Mar 2021 05:47:20

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-05T00:47:12-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd3431d7d-0933-4a88-86f6-78267319cb71'	System	05 Mar 2021 05:47:20
User entered 'No (N)'	System	05 Mar 2021 05:47:20

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-05T00:47:18-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'd3431d7d-0933-4a88-86f6-78267319cb71'	System	05 Mar 2021 05:47:20
User entered '05 Mar 2021 00:47:18'	System	05 Mar 2021 05:47:20

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-12T00:02:41-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '5fbe732f-78b6-4571-bab2-9fba75225ac'	System	12 Mar 2021 05:03:52
User entered 'No (N)'	System	12 Mar 2021 05:03:52

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-12T00:02:45-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '5fbe732f-78b6-4571-bab2-9fba75225ac'	System	12 Mar 2021 05:03:52
User entered 'No (N)'	System	12 Mar 2021 05:03:52

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-12T00:02:51-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '5fbe732f-78b6-4571-bab2-9fba75225ac'	System	12 Mar 2021 05:03:52
User entered '12 Mar 2021 00:02:51'	System	12 Mar 2021 05:03:52

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-21T12:12:22-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1c472335-696f-4019-b73e-6afd8be4d121'	System	21 Mar 2021 16:12:57
User entered 'No (N)'	System	21 Mar 2021 16:12:57

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-21T12:12:25-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1c472335-696f-4019-b73e-6afd8be4d121'	System	21 Mar 2021 16:12:57
User entered 'No (N)'	System	21 Mar 2021 16:12:57

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-21T12:12:29-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '1c472335-696f-4019-b73e-6afd8be4d121'	System	21 Mar 2021 16:12:57
User entered '21 Mar 2021 12:12:29'	System	21 Mar 2021 16:12:57

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-26T08:40:58-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'bf07440b-454a-41db-9c93-6a777508eb8e' User entered 'No (N)'	System	26 Mar 2021 12:41:08
	System	26 Mar 2021 12:41:08

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-26T08:41:02-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'bf07440b-454a-41db-9c93-6a777508eb8e' User entered 'No (N)'	System	26 Mar 2021 12:41:08
	System	26 Mar 2021 12:41:08

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-26T08:41:06-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'bf07440b-454a-41db-9c93-6a777508eb8e' User entered '26 Mar 2021 08:41:06'	System	26 Mar 2021 12:41:08
	System	26 Mar 2021 12:41:08

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-05T17:40:46-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'db649702-6034-4364-896e-cb849452defb'	System	05 Apr 2021 21:40:57
User entered 'No (N)'	System	05 Apr 2021 21:40:57

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-05T17:40:50-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'db649702-6034-4364-896e-cb849452defb'	System	05 Apr 2021 21:40:57
User entered 'No (N)'	System	05 Apr 2021 21:40:57

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-05T17:40:54-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'db649702-6034-4364-896e-cb849452defb'	System	05 Apr 2021 21:40:57
User entered '05 Apr 2021 17:40:54'	System	05 Apr 2021 21:40:57

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-09T06:55:47-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '5bc28e67-0921-4080-88c4-29ca32004737'	System	09 Apr 2021 10:55:58
User entered 'No (N)'	System	09 Apr 2021 10:55:58

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-09T06:55:52-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '5bc28e67-0921-4080-88c4-29ca32004737'	System	09 Apr 2021 10:55:58
User entered 'No (N)'	System	09 Apr 2021 10:55:58

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-09T06:55:56-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '5bc28e67-0921-4080-88c4-29ca32004737'	System	09 Apr 2021 10:55:58
User entered '09 Apr 2021 06:55:56'	System	09 Apr 2021 10:55:58

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-19T18:50:45-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'ded023e7-c51b-4604-8a66-9d977d520763'	System	19 Apr 2021 22:50:56
User entered 'No (N)'	System	19 Apr 2021 22:50:56

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-19T18:50:49-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'ded023e7-c51b-4604-8a66-9d977d520763'	System	19 Apr 2021 22:50:56
User entered 'No (N)'	System	19 Apr 2021 22:50:56

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-19T18:50:53-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: 'ded023e7-c51b-4604-8a66-9d977d520763'	System	19 Apr 2021 22:50:56
User entered '19 Apr 2021 18:50:53'	System	19 Apr 2021 22:50:56

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-26T17:59:18-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86e00a78-b325-4019-a548-e3aa9ccdf1f7'	System	26 Apr 2021 21:59:28
User entered 'No (N)'	System	26 Apr 2021 21:59:28

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-26T17:59:22-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86e00a78-b325-4019-a548-e3aa9ccdf1f7'	System	26 Apr 2021 21:59:28
User entered 'No (N)'	System	26 Apr 2021 21:59:28

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-26T17:59:25-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '86e00a78-b325-4019-a548-e3aa9ccdf1f7'	System	26 Apr 2021 21:59:28
User entered '26 Apr 2021 17:59:25'	System	26 Apr 2021 21:59:28

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-30T00:58:38-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '028502f7-554c-4936-af1e-a13572e65fc7'	System	30 Apr 2021 04:58:54
User entered 'No (N)'	System	30 Apr 2021 04:58:54

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

Have you been exposed to someone with 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 (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-30T00:58:45-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '028502f7-554c-4936-af1e-a13572e65fc7'	System	30 Apr 2021 04:58:54
User entered 'No (N)'	System	30 Apr 2021 04:58:54

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-04-30T00:58:49-04:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '028502f7-554c-4936-af1e-a13572e65fc7' User entered '30 Apr 2021 00:58:49'	System	30 Apr 2021 04:58:54
	System	30 Apr 2021 04:58:54

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:57:33

US3472013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:57:33
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:57:33

US3472013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:43:03

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:45:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-02T09:48:40-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '50f826d9-9561-4591-b182-f231f9e97b1b' User entered 'Yes (Y)'	System	02 Mar 2021 14:49:01
	System	02 Mar 2021 14:49:01

US3472013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:43:03

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:45:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-02T09:48:45-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '50f826d9-9561-4591-b182-f231f9e97b1b'	System	02 Mar 2021 14:49:01
User entered 'No (N)'	System	02 Mar 2021 14:49:01

US3472013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:43:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:45:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CDDF0AAF-E161-4DE6-B6C1-820FC5D542F9)', Time: '2021-03-02T09:48:48-05:00', User OID: 'PatientReportedOutcome (US3472013)', ODM File OID: '50f826d9-9561-4591-b182-f231f9e97b1b' User entered '02 Mar 2021 09:48:48'	System	02 Mar 2021 14:49:01
	System	02 Mar 2021 14:49:01

US3472013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:30:40

US3472013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:30:40

US3472013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:30:40

US3472013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:30:40

US3472013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:45:03

US3472013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 02:12:14
User entered 'I'	System	20 Nov 2020 18:45:03

US3472013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	24 Dec 2020 19:17:53

US3472013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '24 Dec 2020'	Jie Ho (b) (4)	24 Dec 2020 19:17:53

US3472013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Contact Made (CONTACT MADE)'	Jie Ho (b) (4)	24 Dec 2020 19:17:53

US3472013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	Jie Ho (b) (4)	24 Dec 2020 19:17:53

US3472013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	24 Dec 2020 19:17:59

US3472013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User entered 'I'	System	24 Dec 2020 19:17:59

US3472013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 17:16:13

US3472013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 17:16:13

US3472013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 17:16:13

US3472013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 17:16:13

US3472013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 17:16:18

US3472013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User entered 'I'	System	23 Jan 2021 17:16:18

US3472013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:06:21

US3472013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:06:21

US3472013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:06:21

US3472013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:06:21

US3472013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:06:25

US3472013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:08:09
User entered 'I'	System	22 Feb 2021 20:06:25

US3472013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:17:44

US3472013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:17:44

US3472013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:17:44

US3472013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'VISIT4'	System	17 Mar 2021 01:17:44

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '16 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '14:50'	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '16 Mar 2021 14:50'	System	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '36.3' C	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '98'	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'bpm'	System	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '16'	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'breaths/min'	System	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '135'	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'mmHg'	System	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '92'	(b) (4), (b) (6)	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'mmHg'	System	31 Mar 2021 15:24:38

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39

US3472013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:25
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:24:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39

US3472013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:17:50

US3472013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:17:50

US3472013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:18:01

US3472013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:18:01

US3472013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered '14:40'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:18:01

US3472013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered '16 Mar 2021 14:40'	System	17 Mar 2021 01:18:01

US3472013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:18:05

US3472013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:39
User entered 'I'	System	17 Mar 2021 01:18:05

US3472013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:51:28

US3472013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:51:28

US3472013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:51:28

US3472013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:51:28

US3472013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:51:33

US3472013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 19:51:33

US3472013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:45:46

US3472013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:45:46

US3472013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[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 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:45:46

US3472013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 04:45:46

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:02

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:20:58
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 13:04:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:34:59

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:02

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 18:58:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:20:58
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 07:30:14
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 're-entered data' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:04:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	12 Apr 2021 13:04:26
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:11:12
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:34:59

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:02

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:02

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:53:28
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	16 Jan 2021 04:46:02

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:53:28
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	16 Jan 2021 04:46:02

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:02

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User entered empty.	System	16 Jan 2021 04:46:02

US3472013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User entered empty.	System	16 Jan 2021 04:46:02

US3472013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:35

US3472013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:35

US3472013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '14:40'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:35

US3472013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User entered '15 Jan 2021 14:40'	System	16 Jan 2021 04:46:35

US3472013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:49

US3472013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:49

US3472013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '14:45'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:46:49

US3472013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:58
User entered '15 Jan 2021 14:45'	System	16 Jan 2021 04:46:49

US3472013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:43:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:31:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Sep 2020 19:48:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 19:48:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 19:48:31
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 19:48:28
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:48:28

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:05
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:09:43
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:09:36
User entered 'USA-US122-2020-mRNA-1273-P301000001'	System	25 Sep 2020 15:09:26
User entered 'New'	(b) (4), (b) (6)	25 Sep 2020 15:09:26

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:41:50
Query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'This was not a symptom of COVID-19. ' (Site from DM).	Jie Ho (b) (4)	05 Nov 2020 20:10:10
User opened query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:36:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Atelectasis, LLT: Atelectasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 19:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 19:52:39
Data point term sent to Coder	System	24 Sep 2020 19:51:54
User entered 'Atelectasis'	(b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 19:51:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 19:51:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 19:51:23
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 19:51:02
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'PV Query: Please confirm hospital discharge date. The discharge summary states 24Sep2020 rather than 23 Sep2020' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:04:55
Query 'PV Query: Please confirm hospital discharge date. The discharge summary states 24Sep2020 rather than 23 Sep2020' answered with 'Confirming this is the correct discharge date. There is one instance in the summary that states the discharge date is 24Sep2020 but all other locations report 23SEP2020. The participant confirms that they were discharged on 23SEP2020.' (Site from Safety).	Jie Ho (b) (4)	14 Oct 2020 18:10:45
User opened query 'PV Query: Please confirm hospital discharge date. The discharge summary states 24Sep2020 rather than 23 Sep2020' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 16:32:52
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 19:51:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 19:51:23
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 19:51:23
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 19:51:02
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:42:30
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Conmeds are logged for the post-operative pain due to this. ' (Site from DM).	Jie Ho (b) (4)	19 Oct 2020 12:55:07
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 02:09:08
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:26:53
User closed query 'PV Query: Please confirm that the surgery was planned prior to study enrollment. If not, please assess if it meets separate AE/SAE reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 13:26:50
User closed query 'PV Query: Please report results of any covid testing done prior to and during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 13:26:45
Query 'PV Query: Please report results of any covid testing done prior to and during hospitalization.' answered with 'No COVID testing prior to or during admission reported.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:14:56
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent 05 October 2020 via email.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:14:33
Query 'PV Query: Please confirm that the surgery was planned prior to study enrollment. If not, please assess if it meets separate AE/SAE reporting criteria.' answered with 'According to the patient, this was a planned procedure.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:04:39
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:15:30
User opened query 'PV Query: Please confirm that the surgery was planned prior to study enrollment. If not, please assess if it meets separate AE/SAE reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:15:21

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please report results of any covid testing done prior to and during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:15:12
User entered 'Postoperative atelectasis leading to prolonged hospitalization due to hypoxia following gastric band surgery on 21 Sep 2020. Participant had O2 saturation in "high 80s" postoperatively, leading to 2 day hospitalization and use of supplemental oxygen, which she was discharged with on 9/23/2020. Atelectasis confirmed on Xray. Followed up with PCP on 9/24/2020 and oxygen discontinued. No ongoing SOB, O2 saturation 96% on assessment.'	(b) (4), (b) (6)	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Sep 2020 19:51:02

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Oesophagitis (excl infective), PT: Oesophagitis, LLT: Esophagitis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 20:39:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 20:39:38
Data point term sent to Coder	System	24 Sep 2020 19:56:04
User entered 'Esophageal swelling'	(b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User entered empty.	System	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:48:49
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:00:03
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Confirming as ongoing.' (Site from DM).	Jie Ho (b) (4)	07 Dec 2020 20:47:17
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 11:50:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '1 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:48:49
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User entered empty.	System	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) (b) (4), (b) (6)	16 Jan 2021 04:48:49
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty; reason for change Data Entry Error	(b) (4)	
	Jie Ho (b) (4)	30 Oct 2020 18:30:39
User entered 'Postoperative esophageal swelling, visualized on CT imaging on 9/24/2020.'	(b) (4), (b) (6)	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User entered '0'	System	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39
User entered 'I'	System	24 Sep 2020 19:55:35

US3472013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:07:39

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 11:52:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 11:52:56
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 01:22:06
User entered 'Meniscus torn, left'	(b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 01:21:36

US3472013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 01:21:36

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:31:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per CDM: Medication taken to treat pain or fever is recorded as 'yes'. Site response on eDiary form (Dose Temp log line #2, #3, #4, #5) indicates 'Medication details will be collected at the upcoming Safety Call Day 8 and reported'. Please provide medication details once the data is available (Safety Call Day 8). Please respond to this query once the data is entered or for clarification. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:12:47
Query 'Per CDM: Medication taken to treat pain or fever is recorded as 'yes'. Site response on eDiary form (Dose Temp log line #2, #3, #4, #5) indicates 'Medication details will be collected at the upcoming Safety Call Day 8 and reported'. Please provide medication details once the data is available (Safety Call Day 8). Please respond to this query once the data is entered or for clarification. Thank you.' answered with 'Data entered, thank you.' (Site from DM).	Jie Ho (b) (4)	10 Sep 2020 13:44:12
User opened query 'Per CDM: Medication taken to treat pain or fever is recorded as 'yes'. Site response on eDiary form (Dose Temp log line #2, #3, #4, #5) indicates 'Medication details will be collected at the upcoming Safety Call Day 8 and reported'. Please provide medication details once the data is available (Safety Call Day 8). Please respond to this query once the data is entered or for clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:48:42
User entered 'Yes (Y)'	Jie Ho (b) (4)	03 Sep 2020 03:57:57

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: OMALIZUMAB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 06:40:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:40:34
Data point term sent to Coder	System	03 Sep 2020 04:00:21
User entered 'Omalizumab'	Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Asthma'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '375'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'other (OTHER)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Every two weeks'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 03:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 03:59:54
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Jie Ho (b) (4)	03 Sep 2020 03:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 03:59:35
User entered empty.	Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '10 Feb 2020'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 03:59:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 04:01:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 04:01:36
Data point term sent to Coder	System	03 Sep 2020 04:01:21
User entered 'Lexapro'	Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Depression'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '20'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'once daily (QD)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'un UNK 1996'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 04:00:35

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE HYDROCHLORIDE, PRODUCTSYNONYM: CONCERTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 04:11:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 04:11:41
Data point term sent to Coder	System	03 Sep 2020 04:10:23
User entered 'Concerta'	Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	28 Sep 2020 13:51:22
User entered 'Yes (Y)'	Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Depression'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '36'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
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	03 Sep 2020 04:10:02
User entered 'twice daily (BID)' reason for change: Data Entry Error	System	03 Sep 2020 04:10:02
User opened query 'Data is required. Please complete.' (Site from System).	Jie Ho (b) (4)	03 Sep 2020 04:10:02
User entered empty.	System	03 Sep 2020 04:09:47
	Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'un UNK 1998'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Sep 2020 04:10:02
User entered empty.	System	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 04:10:02
User entered empty.	System	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 04:10:02
User entered empty.	System	03 Sep 2020 04:09:47

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 15:34:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:34:41
Data point term sent to Coder	System	03 Sep 2020 04:17:24
User entered 'Trazodone'	Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Sleep Disturbance'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 06:29:11
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	12 Nov 2020 16:55:13
User entered '100' reason for change: Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 16:54:53
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:28:50
User entered '10'	Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'PRN for sleep'. Please review predefined options available for 'Frequency' and confirm or update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:13:04
Query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'PRN for sleep'. Please review predefined options available for 'Frequency' and confirm or update as appropriate.' answered with 'Updated to "as needed", thank you.' (Site from DM).	Jie Ho (b) (4)	10 Sep 2020 12:47:26
User entered 'as needed (PRN)' reason for change: Per Query Resolution	Jie Ho (b) (4)	10 Sep 2020 12:46:59
User opened query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'PRN for sleep'. Please review predefined options available for 'Frequency' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:32:23
User entered 'other (OTHER)'	Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	10 Sep 2020 12:46:59
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	10 Sep 2020 12:46:42
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	10 Sep 2020 12:46:42
User entered 'prn for sleep'	Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'un UNK 2002'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	03 Sep 2020 04:17:08
User entered 'No (N)'	Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 04:17:08
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		03 Sep 2020 04:17:00
User entered empty.	Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 04:17:00

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 13:44:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 13:44:39
Data point term sent to Coder	System	10 Sep 2020 13:44:01
User entered 'acetaminophen'	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Injection site pain'	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '1500'	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'twice daily (BID)'	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '02 Sep 2020'	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '05 Sep 2020'	Jie Ho (b) (4)	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 06:27:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'This solicited event does not meet AE reporting criteria.' (Site from DM).	Jie Ho (b) (4)	12 Nov 2020 16:55:52

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

Was this medication taken for solicited event?

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 timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Jie Ho (b) (4)	12 Nov 2020 14:29:43 10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User entered '2'	System	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User entered '1'	System	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:14
User entered '804 (804)'	System	10 Sep 2020 13:43:31

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 13:29:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 13:29:43
Data point term sent to Coder	System	25 Sep 2020 13:29:21
User entered 'Acetaminophen'	(b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 09:13:51
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'This was not evaluated by PI as clinically significant and therefore not reported.' (Site from DM).	Jie Ho (b) (4)	12 Nov 2020 16:56:33
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:30:11
User entered 'Postoperative Pain'	(b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '500'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Jie Ho (b) (4)	28 Sep 2020 13:52:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '25 Sep 2020' reason for change: New Information	(b) (4)	
	Jie Ho (b) (4)	28 Sep 2020 13:52:24
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User entered empty.	System	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User entered empty.	System	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:10
User entered empty.	System	25 Sep 2020 13:29:18

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 15:23:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 15:23:49
Data point term sent to Coder	System	25 Sep 2020 13:30:21
User entered 'Acetaminophen-Codeine 300-30mg'	(b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 09:22:11
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'This was not evaluated by PI as clinically significant and therefore not reported.' (Site from DM).	Jie Ho (b) (4)	12 Nov 2020 16:56:44
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:30:29
User entered 'Postoperative pain'	(b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Jie Ho (b) (4)	28 Sep 2020 13:52:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '25 Sep 2020' reason for change: New Information	(b) (4)	
	Jie Ho (b) (4)	28 Sep 2020 13:52:44
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User entered empty.	System	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User entered empty.	System	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:06
User entered empty.	System	25 Sep 2020 13:29:56

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 08:19:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 08:19:22
Data point term sent to Coder	System	08 Oct 2020 16:47:44
Coding entries removed.	Jie Ho (b) (4)	08 Oct 2020 16:47:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 06:39:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 06:39:22
Data point term sent to Coder	System	05 Oct 2020 18:53:17
User entered 'Omeprazole'	(b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 08:11:42
Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'Updated, thank you.' (Site from DM).	Jie Ho (b) (4)	08 Oct 2020 16:47:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	08 Oct 2020 16:47:39
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:55:28
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Prophylaxis for GERD FOLLOWING GASTRIC BAND' reason for change: Data Entry Error	(b) (4)	
	Jie Ho (b) (4)	08 Oct 2020 16:47:39
User entered 'GERD prevention following Gastric Band'	(b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '20'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'once daily (QD)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:15:16
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:15:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '21 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 22:15:16
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User entered '1'	System	29 Oct 2020 22:15:16
User entered empty.	System	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User entered '1'	System	29 Oct 2020 22:15:16
User entered empty.	System	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User entered '804 (804)'	System	29 Oct 2020 22:15:16
User entered empty.	System	05 Oct 2020 18:53:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Oct 2020 05:47:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:47:23
Data point term sent to Coder	System	05 Oct 2020 18:54:19
User entered 'Oxycodone'	(b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:22:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'The associated concomitant procedure is reported with the same date. The associated condition is reported in participant Medical History.' (Site from DM).	Jie Ho (b) (4)	30 Nov 2020 01:13:42
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 06:55:54
User entered 'Postoperative pain'	(b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '5'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:16:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '04 Oct 2020' reason for change: New Information	(b) (4)	
User entered '01 Oct 2020' reason for change: New Information	Jie Ho (b) (4)	30 Oct 2020 18:32:34
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:16:08
	(b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User entered empty.	System	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User entered empty.	System	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User entered empty.	System	05 Oct 2020 18:53:32

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:24:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:24:47
Data point term sent to Coder	System	30 Nov 2020 01:25:35
Coding entries removed.	Jie Ho (b) (4)	30 Nov 2020 01:24:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:42:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:42:18
Data point term sent to Coder	System	05 Oct 2020 19:03:37
User entered 'Enoxaparin'	(b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Indication = POSTOPERATIVE DVT RISK. Please review if this indication should be updated to POSTOPERATIVE PROPHYLAXIS DVT. If yes, please update all applicable fields including "Prophylaxis" = YES. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:22:19
Query 'Per DM CLR: Indication = POSTOPERATIVE DVT RISK. Please review if this indication should be updated to POSTOPERATIVE PROPHYLAXIS DVT. If yes, please update all applicable fields including "Prophylaxis" = YES. ' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	30 Nov 2020 01:24:48
User entered 'Yes (Y)' reason for change: Per Query Jie Ho Resolution	(b) (4)	30 Nov 2020 01:24:43
User opened query 'Per DM CLR: Indication = POSTOPERATIVE DVT RISK. Please review if this indication should be updated to POSTOPERATIVE PROPHYLAXIS DVT. If yes, please update all applicable fields including "Prophylaxis" = YES. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 06:54:34
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'POSTOPERATIVE Prophylaxis for DVT' reason for change: Per Query Resolution	(b) (4)	
	Jie Ho (b) (4)	30 Nov 2020 01:24:43
User entered 'Postoperative DVT risk'	(b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '40'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User entered empty.	System	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User entered empty.	System	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:47
User entered empty.	System	05 Oct 2020 19:02:38

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Nov 2020 06:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Nov 2020 06:26:51
Data point term sent to Coder	System	30 Nov 2020 01:25:37
Coding entries removed.	Jie Ho (b) (4)	30 Nov 2020 01:25:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 13:17:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 13:17:31
Data point term sent to Coder	System	05 Oct 2020 19:03:37
User entered 'Apixaban'	(b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Indication = POSTOPERATIVE DVT RISK. Please review if this indication should be updated to POSTOPERATIVE PROPHYLAXIS DVT. If yes, please update all applicable fields including "Prophylaxis" = YES. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:22:23
Query 'Per DM CLR: Indication = POSTOPERATIVE DVT RISK. Please review if this indication should be updated to POSTOPERATIVE PROPHYLAXIS DVT. If yes, please update all applicable fields including "Prophylaxis" = YES. ' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	30 Nov 2020 01:26:01
User entered 'Yes (Y)' reason for change: Per Query Jie Ho Resolution	(b) (4)	30 Nov 2020 01:25:19
User opened query 'Per DM CLR: Indication = POSTOPERATIVE DVT RISK. Please review if this indication should be updated to POSTOPERATIVE PROPHYLAXIS DVT. If yes, please update all applicable fields including "Prophylaxis" = YES. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 06:54:43
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User entered 'POSTOPERATIVE prophylaxis for DVT' reason for change: Per Query Resolution	Jie Ho (b) (4)	30 Nov 2020 01:25:19
User entered 'Postoperative DVT risk'	(b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '2.5'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User entered '02 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 19:03:03

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
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)	21 Oct 2020 14:33:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:33:31
Data point term sent to Coder	System	21 Oct 2020 14:33:01
User entered 'Influenza Vaccination'	(b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Influenza Prophylaxis'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0.5'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User entered empty.	System	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User entered empty.	System	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:41
User entered empty.	System	21 Oct 2020 14:32:07

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:43:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:31:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:28:14

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
DataPoint activated with code reason code Data required.	Jie Ho (b) (4)	05 Oct 2020 14:55:01
DataPoint inactivated with code reason code Data not required.	Jie Ho (b) (4)	05 Oct 2020 14:54:46
User entered '21 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 13:28:32

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
DataPoint activated with code reason code Data required.	Jie Ho (b) (4)	05 Oct 2020 14:55:01
DataPoint inactivated with code reason code Data not required.	Jie Ho (b) (4)	05 Oct 2020 14:54:46
User entered 'Gastric Band Surgery'	(b) (4), (b) (6)	25 Sep 2020 13:28:32

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 08:13:56
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'Medical History updated, thank you.' (Site from DM).	Jie Ho (b) (4)	05 Oct 2020 18:30:35
DataPoint activated with code reason code Data required.	Jie Ho (b) (4)	05 Oct 2020 14:55:01
DataPoint inactivated with code reason code Data not required.	Jie Ho (b) (4)	05 Oct 2020 14:54:46
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:32:53
User entered 'Medical History (MH)'	(b) (4), (b) (6)	25 Sep 2020 13:28:32

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:03

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
	(b) (4)	
DataPoint activated with code reason code Data required.	Jie Ho (b) (4)	05 Oct 2020 14:55:01
DataPoint inactivated with code reason code Data not required.	Jie Ho (b) (4)	05 Oct 2020 14:54:46
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 13:28:32

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:43:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:35
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:48:11

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:43:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:35
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'left gluteus medius tendon repair and reconstruction'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:48:11

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:43:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:35
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:48:11

US3472013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:43:03

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:35
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:48:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'USA-US122-2020-MRNA-1273-P301000001'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'Yes (Y)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'Yes (Y)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered (b) (6)'	System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered (b) (6) '	System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'US'	System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Oct 2020 14:05:23
User entered '2'	System	06 Oct 2020 13:27:11
User entered '1'	System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'USA-US122-2020-MRNA-1273-P301000001'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'Yes (Y)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'Yes (Y)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered (b) (6)'	System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered (b) (6) '	System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'US'	System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Oct 2020 14:05:23
User entered '2'	System	06 Oct 2020 13:27:11
User entered '1'	System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:43:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '25/Sep/2020 11:10'	(b) (4) System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:43:03

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.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'USA-US122-2020-MRNA-1273-P301000001'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'Yes (Y)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'Yes (Y)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered (b) (6)'	System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered (b) (6) '	System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'US'	System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Oct 2020 14:05:23
User entered '2'	System	06 Oct 2020 13:27:11
User entered '1'	System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:43:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '06/Oct/2020 13:27'	(b) (4) System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:43:03

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.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'USA-US122-2020-MRNA-1273-P301000001'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'Yes (Y)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'Yes (Y)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'No (N)'	System	25 Sep 2020 15:09:26

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered (b) (6)'	System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:15
User entered (b) (6) '	System	06 Oct 2020 13:27:11

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:27:01
User entered 'US'	System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Oct 2020 14:05:23
User entered '2'	System	06 Oct 2020 13:27:11
User entered '1'	System	25 Sep 2020 15:10:19

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:43:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered '15/Oct/2020 10:05'	(b) (4) System	15 Oct 2020 14:05:23

US3472013

Folder: SAE USA-US122-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:43:03

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.	Ian Frank (b) (4)	29 Mar 2021 15:36:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:05:23