

US3032305 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:54:48

All time stamps listed in this document are displayed in GMT

US3032305

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

[Participant ID](#)

US3032305

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

US3032305

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3032305

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
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

US3032305

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3032305

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3032305

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Were any significant conditions reported?

Yes ☒
No ☐

US3032305

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Condition	BILATERAL PULMONARY EMBOLISM
Start date (dd MMM yyyy)	UN FEB 2020
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 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

US3032305

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Condition	SUPRAVENTRICULAR ARRHYTHMIAS
Start date (dd MMM yyyy)	UN FEB 2020
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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3032305

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3032305

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032305

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032305

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:51:25

Generated On: 11 Aug 2021 21:54:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 15:45
Height (xxx.x)	165.1 cm
Weight (xxx.x)	67.1 kg
BMI (xxx.x)	24.61662 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032305

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3032305

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Date of assessment (dd MMM yyyy) 21 AUG 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 1985

Date of last menstruation unknown False

US3032305

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

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

OUTINGS IN THE COMMUNITY:
VOLUNTEERING, SHOPPING,
ETC, 6+ DAYS A WEEK

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

19 of 1704

US3032305

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

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	

US3032305

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Nov 2020 22:23:45

Generated On: 11 Aug 2021 21:54:48

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

What was the participant's randomization number? 187676

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 ☒

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Oct 2020 19:43:50

Generated On: 11 Aug 2021 21:54:48

Height	ND - Not Done
Weight	ND - Not Done

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Oct 2020 19:43:50

Generated On: 11 Aug 2021 21:54:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 15:45
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Oct 2020 19:43:50

Generated On: 11 Aug 2021 21:54:48

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)	21 AUG 2020
Time of assessment (00:00-23:59)	17:47 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 17:47
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3032305

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 17:12 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 17:12

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

US3032305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

16:45 (24 HR)

Collection date and time (derived)

21 AUG 2020 16:45

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:42	21 AUG 2020 16:42
Nasopharyngeal Swab 2	No		

US3032305

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 17:47

PC Open Date & Time

21 AUG 2020 17:32

PC Close Date & Time

21 AUG 2020 20:02

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	21 AUG 2020 21:25
PC Open Date & Time	21 AUG 2020 20:57
PC Close Date & Time	22 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 13:36

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:48

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

97.6 °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

23 AUG 2020 12:38

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:48

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 16:13

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:48

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:54

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 15:18

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:48

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

97.4 °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

27 AUG 2020 12:34

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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

21 AUG 2020 17:48

PC Open Date & Time

21 AUG 2020 17:32

PC Close Date & Time

21 AUG 2020 20:02

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 21:26

PC Open Date & Time

21 AUG 2020 20:57

PC Close Date & Time

22 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 13:36

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:38

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 16:13

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 12:54

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 15:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:34

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 17:49
PC Open Date & Time	21 AUG 2020 17:32
PC Close Date & Time	21 AUG 2020 20:02

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 21:26
PC Open Date & Time	21 AUG 2020 20:57
PC Close Date & Time	22 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

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 ☒

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 13:37
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

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

53 of 1704

EAB) (1725)

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:39
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

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 ☒

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 16:13
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

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 ☒

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:55
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

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 ☒

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 15:19
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

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 ☒

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:35
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3032305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:09:22

Generated On: 11 Aug 2021 21:54:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 18:09:22

Generated On: 11 Aug 2021 21:54:48

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)	22 SEP 2020
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 10:27
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 18:09:22

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:09:22

Generated On: 11 Aug 2021 21:54:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3032305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 18:09:22

Generated On: 11 Aug 2021 21:54:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

22 SEP 2020 11:00

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:42	22 SEP 2020 10:42
Nasopharyngeal Swab 2	No		

US3032305

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:51:25

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:51:25

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 19:43:50

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 15:04:27

Generated On: 11 Aug 2021 21:54:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 15:04:27

Generated On: 11 Aug 2021 21:54:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 08:45
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 15:04:27

Generated On: 11 Aug 2021 21:54:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3032305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 15:04:27

Generated On: 11 Aug 2021 21:54:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

08:53 (24 HR)

Collection date and time (derived)

19 OCT 2020 08:53

US3032305

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 15:04:27

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

25 OCT 2020 14:25:23

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

28 OCT 2020 08:07:32

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

04 NOV 2020 19:58:01

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 11:30:28

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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	25 NOV 2020 19:02:27
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

29 NOV 2020 18:57:41

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 15:42:50

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 07:40:46

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 20:12:55

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 21:03:49

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 14:38:11

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 12:15:31

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 10:13:48

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 12:10:10

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 07:50:50

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 20:55:38

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

14 FEB 2021 18:12:28

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 12:28:01

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 15:01:52

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 11:58:33

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 11:25:01

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

21 MAR 2021 19:13:19

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

05 APR 2021 15:32:36

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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	11 APR 2021 07:35:28
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 14:43:08

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 09:18:03

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 18:27:03

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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°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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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°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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐ Yes ☐

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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°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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Patient Cloud Close Date & Time	19 AUG 2021 23:59
---	-------------------

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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°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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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="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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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="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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 <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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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°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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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°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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 691

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

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

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

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

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

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

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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 ☐

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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="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"/>

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3032305

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:54:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 15:02:05

US3032305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Nov 2020 15:53:29

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Nov 2020 15:53:29

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Dec 2020 15:56:08

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Dec 2020 15:56:08

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:40:23

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:40:23

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:40:23

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:40:23

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032305

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

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.

US3032305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

23 MAR 2021 14:25

US3032305

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:25:05

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 18:25:05

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032305

Folder: Covid-19 Assessment (2)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:48

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"/>

US3032305

Folder: Covid-19 Assessment (2)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:54:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Nov 2020 20:30:00

Generated On: 11 Aug 2021 21:54:48

Date of Contact	10 SEP 2020
Time of Contact	13:00
Date and Time of Contact (derived)	10 SEP 2020 13:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3032305

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

Form: Visit Date

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

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

Visit date (dd MMM yyyy)	23 FEB 2021
--------------------------	-------------

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

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

US3032305

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:40:23

Generated On: 11 Aug 2021 21:54:48

Date of updated informed consent (<i>dd MMM yyyy</i>)	23 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	23 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3032305

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

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

US3032305

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	14:54 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 14:54
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3032305

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 16:05
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3032305

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

Form: Physical Examination

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3032305

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

Form: Exposure

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 15:34 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 15:34

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

What was the frequency of the study treatment dosing? ONCE

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

US3032305

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

23 FEB 2021 14:25

US3032305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	23 FEB 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	14:34
---------------------------------	-------

Collection Date and Time (derived)	23 FEB 2021 14:34
------------------------------------	-------------------

US3032305

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

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:05:34

Generated On: 11 Aug 2021 21:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032305

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:05:35

Generated On: 11 Aug 2021 21:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032305

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:05:35

Generated On: 11 Aug 2021 21:54:48

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

US3032305

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:15 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 14:15
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	57 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032305

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

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.

US3032305

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:44:55

Generated On: 11 Aug 2021 21:54:48

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3032305

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Nov 2020 15:53:29

Generated On: 11 Aug 2021 21:54:48

AEID	
Adverse event	COVID-19 INFECTION
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)	08 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)	08 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Nov 2020 15:53:29

Generated On: 11 Aug 2021 21:54:48

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 checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

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

Yes ☒

No ☐

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

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication METOPROLOLOL ER

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
SUPRAVENTRICULAR
ARRHYTHMIA

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

313 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
HYPOTHYROIDISM

Dose per administration 112

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)

315 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2011
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"/>

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

317 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
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"/>

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication ELIQUIS

Prophylaxis Yes ☒
No ☐

Indication MEDICAL HISTORY:
PULMONARY EMBOLISM
PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

319 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication ROPINIROLE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: RESTLESS
LEG SYNDROME

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)

321 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication CALCIUM + VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
OSTEOPENIA

Dose per administration 600/400

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

If dose unit is Other, specify MG/IU

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)

323 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: ACID
REFLUX

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)

325 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication APIXABAN

Prophylaxis Yes ☒
No ☐

Indication PULMONARY EMBOLISM
PROPHYLAXIS

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)

327 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

329 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Jan 2021 16:54:13

Generated On: 11 Aug 2021 21:54:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)		10 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)		10 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"/>

US3032305

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 18:08:51

Generated On: 11 Aug 2021 21:54:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3032305

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 17 Nov 2020 15:53:29

Generated On: 11 Aug 2021 21:54:48

Date of dosing discontinuation (dd MMM yyyy) 08 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3032305

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:54:48

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 ☐

Audit

US3032305 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032305

Form: Participant Creation

Generated On: 11 Aug 2021 21:54:48

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'US3032305'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:04:12

US3032305

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:15:55
	(b) (4)	

US3032305

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:04:13

US3032305

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:15:55

US3032305

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'SCRN'	System	22 Aug 2020 00:15:55

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered (b) (6)1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:04:14

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '71'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'YEARS'	System	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '71'	System	21 Aug 2020 22:20:27

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Female (F)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17
	(b) (4)	

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17
	(b) (4)	

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17
	(b) (4)	

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:17

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:27
	(b) (4)	

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Aug 2020'	System	21 Aug 2020 22:20:27

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2020'	System	21 Aug 2020 22:20:27

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 22:20:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 22:20:31
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	21 Aug 2020 22:20:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 22:20:27
User entered empty.	System	21 Aug 2020 22:20:27
	Kelsey Kelley (b) (4)	21 Aug 2020 22:20:27
	(b) (4)	

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:27

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:27
	(b) (4)	

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:27
	(b) (4)	

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:27

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:04:13

US3032305

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'I'	System	21 Aug 2020 22:20:36

US3032305

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:36
	(b) (4)	

US3032305

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:54:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:29:48

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User closed query 'Per DM CLR: Please specify the lung laterality in PULMONARY EMBOLISM. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 08:24:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 23:05:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 23:05:36
Data point term sent to Coder	System	30 Sep 2020 23:04:18
Query 'Per DM CLR: Please specify the lung laterality in PULMONARY EMBOLISM. Review and update Med History eCRF as appropriate. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	30 Sep 2020 23:03:35
Coding entries removed.	Linden DeBoer (b) (4) (b) (4)	30 Sep 2020 23:03:29
User entered 'BILATERAL PULMONARY EMBOLISM' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	30 Sep 2020 23:03:29
User opened query 'Per DM CLR: Please specify the lung laterality in PULMONARY EMBOLISM. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 00:47:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 00:35:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 00:35:24
Data point term sent to Coder	System	22 Aug 2020 00:33:42
User entered 'pulmonary embolism'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un Feb 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	30 Sep 2020 23:03:47
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 14:28:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 14:28:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	26 Aug 2020 14:28:56
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 00:33:01
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
Signature has been broken.	Linden DeBoer (b) (4)	20 Nov 2020 20:44:41
User entered 'UN Feb 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	20 Nov 2020 20:44:41
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:18:15
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' answered with 'data is correct per patient' (Site from DM).	Linden DeBoer (b) (4)	23 Oct 2020 19:34:27
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 08:47:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un Apr 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	30 Sep 2020 23:03:47
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Feb 2020'	System	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2020'	System	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Feb 2020'	System	20 Nov 2020 20:44:41
User entered 'Apr 2020'	System	30 Sep 2020 23:03:47
User entered empty.	System	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2020'	System	30 Sep 2020 23:03:47
User entered empty.	System	22 Aug 2020 00:33:01

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Arrhythmia supraventricular, LLT: Arrhythmia supraventricular - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 04:51:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 04:51:21
Data point term sent to Coder	System	22 Aug 2020 00:33:42
User entered 'supraventricular arrhythmias'	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un Feb 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 14:29:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 14:29:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	26 Aug 2020 14:29:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Aug 2020 00:33:41
User entered empty.	System	22 Aug 2020 00:33:41
	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:41
	(b) (4)	

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Feb 2020'	System	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2020'	System	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:33:41

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
Data point term sent to Coder	System	22 Aug 2020 00:34:43
User entered 'hypothyroidism'	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2009'	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Jan 2009'	System	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2009'	System	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:33:54

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
Data point term sent to Coder	System	22 Aug 2020 00:34:43
User entered 'hypercholesterolemia'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Jan 2010'	System	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2010'	System	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:05

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
Data point term sent to Coder	System	22 Aug 2020 00:34:43
User entered 'restless leg syndrome'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2018'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Jan 2018'	System	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2018'	System	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:19

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
Data point term sent to Coder	System	22 Aug 2020 00:34:43
User entered 'osteoarthritis in bilateral hands'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Jan 2010'	System	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2010'	System	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:31

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:35:24
Data point term sent to Coder	System	22 Aug 2020 00:34:43
User entered 'postmenopausal'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 1985'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:41
	(b) (4)	

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Jan 1985'	System	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '1985'	System	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:41

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:37:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:37:23
Data point term sent to Coder	System	22 Aug 2020 00:35:45
User entered 'osteopenia'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2016'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Jan 2016'	System	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2016'	System	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:34:51

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:37:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 00:37:23
Data point term sent to Coder	System	22 Aug 2020 00:35:45
User entered 'acid reflux'	Kelsey Kelley (b) (4)	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:03
	(b) (4)	

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'Jan 2010'	System	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '2010'	System	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	22 Aug 2020 00:35:03

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41
	(b) (4)	

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '15:45'	Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '21 Aug 2020 15:45'	System	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '165.1' cm	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41
DataPoint set to visible.	(b) (4) System	21 Aug 2020 22:20:36

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '67.1' kg	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41
DataPoint set to visible.	(b) (4) System	21 Aug 2020 22:20:36

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
Amendment Manager: User entered '24.61662'	System	17 Sep 2020 00:19:29
User entered '24.6'	System	22 Aug 2020 00:31:41
DataPoint set to visible.	System	21 Aug 2020 22:20:36

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'kg/m2'	System	22 Aug 2020 00:31:41
DataPoint set to visible.	System	21 Aug 2020 22:20:36

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:20:47
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:31:08
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:31:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:31:02
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:29:30
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:08:52
User entered '36.7' C	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:31:02
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:31:02
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41
	(b) (4)	

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:31:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 15:31:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '68'	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41
	(b) (4)	

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'bpm'	System	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:31:02
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:31:02
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '14'	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41
	(b) (4)	

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'breaths/min'	System	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:31:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 15:31:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '108'	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41
	(b) (4)	

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'mmHg'	System	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:31:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 15:31:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '66'	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 00:31:41
	(b) (4)	

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'mmHg'	System	22 Aug 2020 00:31:41

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52

US3032305

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52

US3032305

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:27:40

US3032305

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	Kelsey Kelley (b) (4)	22 Aug 2020 00:27:40

US3032305

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:07
	(b) (4)	

US3032305

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:07

US3032305

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:54:48

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:30:07

US3032305

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:54:48

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:07

US3032305

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:30:07

US3032305

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:54:48

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:07
	(b) (4)	

US3032305

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'un UNK 1985'	Kelsey Kelley (b) (4)	22 Aug 2020 00:30:07

US3032305

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:54:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:30:07

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'outings in the community: volunteering, shopping, etc, 6+ days a week'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'I'	Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:28:48

US3032305

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:17

US3032305

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:17
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:17

US3032305

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'VISIT1'	System	22 Aug 2020 00:30:17

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:54:22

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '187676'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:54:22

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 21:54:22

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:48

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:30:48

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:48

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:48

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:30:48

US3032305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:48

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:23:45
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	02 Nov 2020 08:49:31
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4)	29 Oct 2020 21:37:35
User entered 'No (N)'	(b) (4)	
User entered 'No (N)'	Linden DeBoer (b) (4)	29 Oct 2020 21:37:31
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:28:32
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:14:08

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:05:19
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:30
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:23
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:56:01
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:08:52
User entered '165.1' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	13 Oct 2020 14:43:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	Kelsey Kelley (b) (4)	13 Oct 2020 14:43:23
	(b) (4)	
User entered '67.1' kg	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:05:19
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:30
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:23
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:56:01
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:08:52
User entered '165.1' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	13 Oct 2020 14:43:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	Kelsey Kelley (b) (4)	13 Oct 2020 14:43:23
	(b) (4)	
User entered '67.1' kg	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '15:45'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '21 Aug 2020 15:45'	System	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '62'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'bpm'	System	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'breaths/min'	System	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '108'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'mmHg'	System	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '66'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'mmHg'	System	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:05:19
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:30
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:43:23
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:56:01
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:08:52
User entered '165.1' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:35:59

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	13 Oct 2020 14:43:23
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	13 Oct 2020 14:43:23
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered '67.1' kg	Kelsey Kelley (b) (4)	22 Aug 2020 00:35:59
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '17:47'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '21 Aug 2020 17:47'	System	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '52'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'bpm'	System	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'breaths/min'	System	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '135'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'mmHg'	System	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '77'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'mmHg'	System	22 Aug 2020 00:36:27

US3032305

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:32:15

US3032305

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:32:15

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:53

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:53
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:53
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 22:20:53

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:53
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '17:12'	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 22:20:53
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '21 Aug 2020 17:12'	System	21 Aug 2020 22:20:53

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	21 Aug 2020 22:20:53

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'ONCE'	System	21 Aug 2020 22:20:53

US3032305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 22:20:53

US3032305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:37:00

US3032305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:37:00
	(b) (4)	

US3032305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '16:45'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:37:00

US3032305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '21 Aug 2020 16:45'	System	22 Aug 2020 00:37:00

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '21 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '16:42'	Kelsey Kelley (b) (4)	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '21 Aug 2020 16:42'	System	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Aug 2020 00:37:14

US3032305

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:37:34

US3032305

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'I'	System	22 Aug 2020 00:37:34

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:47:27', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '23a84a0f-d8b8-40ee-ab81-2a1e1e797532'	System	21 Aug 2020 22:47:54
User entered 'Yes (Y)'	System	21 Aug 2020 22:47:54

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:47:37', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '23a84a0f-d8b8-40ee-ab81-2a1e1e797532'	System	21 Aug 2020 22:47:54
User entered '97.8'	System	21 Aug 2020 22:47:54

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:47:42', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '23a84a0f-d8b8-40ee-ab81-2a1e1e797532'	System	21 Aug 2020 22:47:54
User entered 'No (N)'	System	21 Aug 2020 22:47:54

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:47:52', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '23a84a0f-d8b8-40ee-ab81-2a1e1e797532'	System	21 Aug 2020 22:47:54
User entered '21 Aug 2020 17:47'	System	21 Aug 2020 22:47:54

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 17:32'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 20:02'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:25:20', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '170bb332-319b-4b8a-9dd2-8197715da88f'	System	22 Aug 2020 02:28:46
User entered 'Yes (Y)'	System	22 Aug 2020 02:28:46

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:25:30', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '170bb332-319b-4b8a-9dd2-8197715da88f' User entered '97.8'	System	22 Aug 2020 02:28:46
	System	22 Aug 2020 02:28:46

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:25:33', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '170bb332-319b-4b8a-9dd2-8197715da88f'	System	22 Aug 2020 02:28:46
User entered 'No (N)'	System	22 Aug 2020 02:28:46

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:25:39', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '170bb332-319b-4b8a-9dd2-8197715da88f'	System	22 Aug 2020 02:28:46
User entered '21 Aug 2020 21:25'	System	22 Aug 2020 02:28:46

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 20:57'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 2'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:35:41', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'fc7e9ce1-3ae9-4b0e-b530-e8208eabd261'	System	22 Aug 2020 18:36:04
User entered 'Yes (Y)'	System	22 Aug 2020 18:36:04

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:35:51', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'fc7e9ce1-3ae9-4b0e-b530-e8208eabd261'	System	22 Aug 2020 18:36:04
User entered '97.6'	System	22 Aug 2020 18:36:04

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:35:55', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'fc7e9ce1-3ae9-4b0e-b530-e8208eabd261'	System	22 Aug 2020 18:36:04
User entered 'No (N)'	System	22 Aug 2020 18:36:04

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:02', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'fc7e9ce1-3ae9-4b0e-b530-e8208eabd261'	System	22 Aug 2020 18:36:04
User entered '22 Aug 2020 13:36'	System	22 Aug 2020 18:36:04

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 3'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:37:55', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a50b4f21-cd1d-44fb-8141-d4522b161bcf'	System	23 Aug 2020 17:38:16
User entered 'Yes (Y)'	System	23 Aug 2020 17:38:16

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:03', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a50b4f21-cd1d-44fb-8141-d4522b161bcf'	System	23 Aug 2020 17:38:16
User entered '97.6'	System	23 Aug 2020 17:38:16

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:06', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a50b4f21-cd1d-44fb-8141-d4522b161bcf'	System	23 Aug 2020 17:38:16
User entered 'No (N)'	System	23 Aug 2020 17:38:16

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:12', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a50b4f21-cd1d-44fb-8141-d4522b161bcf'	System	23 Aug 2020 17:38:16
User entered '23 Aug 2020 12:38'	System	23 Aug 2020 17:38:16

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 4'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:12:52', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'cd6a7ac2-5ef8-4cef-b9b0-041811d5a447'	System	24 Aug 2020 21:13:13
User entered 'Yes (Y)'	System	24 Aug 2020 21:13:13

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:12:59', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'cd6a7ac2-5ef8-4cef-b9b0-041811d5a447'	System	24 Aug 2020 21:13:13
User entered '96.8'	System	24 Aug 2020 21:13:13

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:03', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'cd6a7ac2-5ef8-4cef-b9b0-041811d5a447'	System	24 Aug 2020 21:13:13
User entered 'No (N)'	System	24 Aug 2020 21:13:13

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:08', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'cd6a7ac2-5ef8-4cef-b9b0-041811d5a447'	System	24 Aug 2020 21:13:13
User entered '24 Aug 2020 16:13'	System	24 Aug 2020 21:13:13

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 5'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:23', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'dc3af42b-da9f-4661-a2c3-376c8bc88e5c'	System	25 Aug 2020 17:54:41
User entered 'Yes (Y)'	System	25 Aug 2020 17:54:41

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:29', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'dc3af42b-da9f-4661-a2c3-376c8bc88e5c'	System	25 Aug 2020 17:54:41
User entered '97.5'	System	25 Aug 2020 17:54:41

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:33', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'dc3af42b-da9f-4661-a2c3-376c8bc88e5c'	System	25 Aug 2020 17:54:41
User entered 'No (N)'	System	25 Aug 2020 17:54:41

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:37', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'dc3af42b-da9f-4661-a2c3-376c8bc88e5c'	System	25 Aug 2020 17:54:41
User entered '25 Aug 2020 12:54'	System	25 Aug 2020 17:54:41

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 6'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:18:29', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '261a13fd-2891-40f0-8336-18d9c7e0d27b'	System	26 Aug 2020 20:18:51
User entered 'Yes (Y)'	System	26 Aug 2020 20:18:51

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:18:40', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '261a13fd-2891-40f0-8336-18d9c7e0d27b'	System	26 Aug 2020 20:18:51
User entered '98.3'	System	26 Aug 2020 20:18:51

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:18:44', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '261a13fd-2891-40f0-8336-18d9c7e0d27b'	System	26 Aug 2020 20:18:51
User entered 'No (N)'	System	26 Aug 2020 20:18:51

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:18:49', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '261a13fd-2891-40f0-8336-18d9c7e0d27b'	System	26 Aug 2020 20:18:51
User entered '26 Aug 2020 15:18'	System	26 Aug 2020 20:18:51

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 7'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:04', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '300f5b4b-01c6-4e45-9a60-35bfe487dce8'	System	27 Aug 2020 17:34:31
User entered 'Yes (Y)'	System	27 Aug 2020 17:34:31

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:12', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '300f5b4b-01c6-4e45-9a60-35bfe487dce8'	System	27 Aug 2020 17:34:31
User entered '97.4'	System	27 Aug 2020 17:34:31

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:16', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '300f5b4b-01c6-4e45-9a60-35bfe487dce8'	System	27 Aug 2020 17:34:31
User entered 'No (N)'	System	27 Aug 2020 17:34:31

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:28', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '300f5b4b-01c6-4e45-9a60-35bfe487dce8'	System	27 Aug 2020 17:34:31
User entered '27 Aug 2020 12:34'	System	27 Aug 2020 17:34:31

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:10', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b1e3f735-5e24-420d-a0a5-42aafa422bf5'	System	21 Aug 2020 22:48:35
User entered 'None (1)'	System	21 Aug 2020 22:48:35

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:15', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b1e3f735-5e24-420d-a0a5-42aafa422bf5'	System	21 Aug 2020 22:48:35
User entered 'No (N)'	System	21 Aug 2020 22:48:35

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:18', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b1e3f735-5e24-420d-a0a5-42aafa422bf5'	System	21 Aug 2020 22:48:35
User entered 'No (N)'	System	21 Aug 2020 22:48:35

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:25', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b1e3f735-5e24-420d-a0a5-42aafa422bf5'	System	21 Aug 2020 22:48:35
User entered 'None (1)'	System	21 Aug 2020 22:48:35

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:30', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b1e3f735-5e24-420d-a0a5-42aafa422bf5'	System	21 Aug 2020 22:48:35
User entered '21 Aug 2020 17:48'	System	21 Aug 2020 22:48:35

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 17:32'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 20:02'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:25:13', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f8e2197c-b36c-4e00-837a-bd4b0ee4b735'	System	22 Aug 2020 02:28:51
User entered 'None (1)'	System	22 Aug 2020 02:28:51

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:25:55', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f8e2197c-b36c-4e00-837a-bd4b0ee4b735'	System	22 Aug 2020 02:28:51
User entered 'No (N)'	System	22 Aug 2020 02:28:51

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:25:59', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f8e2197c-b36c-4e00-837a-bd4b0ee4b735'	System	22 Aug 2020 02:28:51
User entered 'No (N)'	System	22 Aug 2020 02:28:51

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:04', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f8e2197c-b36c-4e00-837a-bd4b0ee4b735'	System	22 Aug 2020 02:28:51
User entered 'None (1)'	System	22 Aug 2020 02:28:51

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:09', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f8e2197c-b36c-4e00-837a-bd4b0ee4b735'	System	22 Aug 2020 02:28:51
User entered '21 Aug 2020 21:26'	System	22 Aug 2020 02:28:51

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 20:57'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 2'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:10', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'af2e0bd2-c178-421f-8ae9-45a131030380'	System	22 Aug 2020 18:36:33
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 18:36:33

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:14', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'af2e0bd2-c178-421f-8ae9-45a131030380'	System	22 Aug 2020 18:36:33
User entered 'No (N)'	System	22 Aug 2020 18:36:33

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:16', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'af2e0bd2-c178-421f-8ae9-45a131030380'	System	22 Aug 2020 18:36:33
User entered 'No (N)'	System	22 Aug 2020 18:36:33

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:23', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'af2e0bd2-c178-421f-8ae9-45a131030380'	System	22 Aug 2020 18:36:33
User entered 'None (1)'	System	22 Aug 2020 18:36:33

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:30', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'af2e0bd2-c178-421f-8ae9-45a131030380'	System	22 Aug 2020 18:36:33
User entered '22 Aug 2020 13:36'	System	22 Aug 2020 18:36:33

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 3'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:26', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'bd01fb5f-003a-4b3f-99a5-c42d439970cc'	System	23 Aug 2020 17:38:52
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 17:38:52

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:29', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'bd01fb5f-003a-4b3f-99a5-c42d439970cc'	System	23 Aug 2020 17:38:52
User entered 'No (N)'	System	23 Aug 2020 17:38:52

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:32', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'bd01fb5f-003a-4b3f-99a5-c42d439970cc'	System	23 Aug 2020 17:38:52
User entered 'No (N)'	System	23 Aug 2020 17:38:52

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:42', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'bd01fb5f-003a-4b3f-99a5-c42d439970cc'	System	23 Aug 2020 17:38:52
User entered 'None (1)'	System	23 Aug 2020 17:38:52

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:50', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'bd01fb5f-003a-4b3f-99a5-c42d439970cc'	System	23 Aug 2020 17:38:52
User entered '23 Aug 2020 12:38'	System	23 Aug 2020 17:38:52

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 4'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:12', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0c6ad878-4b69-4ec8-8c64-6616e519d90f'	System	24 Aug 2020 21:13:30
User entered 'None (1)'	System	24 Aug 2020 21:13:30

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:15', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0c6ad878-4b69-4ec8-8c64-6616e519d90f'	System	24 Aug 2020 21:13:30
User entered 'No (N)'	System	24 Aug 2020 21:13:30

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:18', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0c6ad878-4b69-4ec8-8c64-6616e519d90f'	System	24 Aug 2020 21:13:30
User entered 'No (N)'	System	24 Aug 2020 21:13:30

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:21', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0c6ad878-4b69-4ec8-8c64-6616e519d90f'	System	24 Aug 2020 21:13:30
User entered 'None (1)'	System	24 Aug 2020 21:13:30

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:26', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0c6ad878-4b69-4ec8-8c64-6616e519d90f'	System	24 Aug 2020 21:13:30
User entered '24 Aug 2020 16:13'	System	24 Aug 2020 21:13:30

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 5'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:41', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2f6f6fe7-ca10-48a9-9a75-2d68961b1406'	System	25 Aug 2020 17:54:57
User entered 'None (1)'	System	25 Aug 2020 17:54:57

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:44', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2f6f6fe7-ca10-48a9-9a75-2d68961b1406'	System	25 Aug 2020 17:54:57
User entered 'No (N)'	System	25 Aug 2020 17:54:57

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:46', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2f6f6fe7-ca10-48a9-9a75-2d68961b1406'	System	25 Aug 2020 17:54:57
User entered 'No (N)'	System	25 Aug 2020 17:54:57

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:49', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2f6f6fe7-ca10-48a9-9a75-2d68961b1406'	System	25 Aug 2020 17:54:57
User entered 'None (1)'	System	25 Aug 2020 17:54:57

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:53', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2f6f6fe7-ca10-48a9-9a75-2d68961b1406'	System	25 Aug 2020 17:54:57
User entered '25 Aug 2020 12:54'	System	25 Aug 2020 17:54:57

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 6'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:18:52', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '39400bf1-d3ee-49e7-b859-2af89a93d245'	System	26 Aug 2020 20:19:07
User entered 'None (1)'	System	26 Aug 2020 20:19:07

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:18:54', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '39400bf1-d3ee-49e7-b859-2af89a93d245'	System	26 Aug 2020 20:19:07
User entered 'No (N)'	System	26 Aug 2020 20:19:07

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:18:56', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '39400bf1-d3ee-49e7-b859-2af89a93d245'	System	26 Aug 2020 20:19:07
User entered 'No (N)'	System	26 Aug 2020 20:19:07

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:18:58', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '39400bf1-d3ee-49e7-b859-2af89a93d245'	System	26 Aug 2020 20:19:07
User entered 'None (1)'	System	26 Aug 2020 20:19:07

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:04', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '39400bf1-d3ee-49e7-b859-2af89a93d245'	System	26 Aug 2020 20:19:07
User entered '26 Aug 2020 15:19'	System	26 Aug 2020 20:19:07

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 7'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:33', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b77c95e0-190c-42ff-afb1-6a2ad4839e84'	System	27 Aug 2020 17:34:47
User entered 'None (1)'	System	27 Aug 2020 17:34:47

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:36', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b77c95e0-190c-42ff-afb1-6a2ad4839e84'	System	27 Aug 2020 17:34:47
User entered 'No (N)'	System	27 Aug 2020 17:34:47

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:38', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b77c95e0-190c-42ff-afb1-6a2ad4839e84'	System	27 Aug 2020 17:34:47
User entered 'No (N)'	System	27 Aug 2020 17:34:47

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:40', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b77c95e0-190c-42ff-afb1-6a2ad4839e84'	System	27 Aug 2020 17:34:47
User entered 'None (1)'	System	27 Aug 2020 17:34:47

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:43', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b77c95e0-190c-42ff-afb1-6a2ad4839e84'	System	27 Aug 2020 17:34:47
User entered '27 Aug 2020 12:34'	System	27 Aug 2020 17:34:47

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:37', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67940ba-d91a-4231-8c01-ee7d9368c20c'	System	21 Aug 2020 22:49:13
User entered 'None (0)'	System	21 Aug 2020 22:49:13

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:42', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67940ba-d91a-4231-8c01-ee7d9368c20c'	System	21 Aug 2020 22:49:13
User entered 'None (0)'	System	21 Aug 2020 22:49:13

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:44', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67940ba-d91a-4231-8c01-ee7d9368c20c'	System	21 Aug 2020 22:49:13
User entered 'None (0)'	System	21 Aug 2020 22:49:13

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:47', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67940ba-d91a-4231-8c01-ee7d9368c20c'	System	21 Aug 2020 22:49:13
User entered 'None (0)'	System	21 Aug 2020 22:49:13

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:49', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67940ba-d91a-4231-8c01-ee7d9368c20c'	System	21 Aug 2020 22:49:13
User entered 'None (0)'	System	21 Aug 2020 22:49:13

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:48:52', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67940ba-d91a-4231-8c01-ee7d9368c20c'	System	21 Aug 2020 22:49:13
User entered 'None (0)'	System	21 Aug 2020 22:49:13

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:49:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67940ba-d91a-4231-8c01-ee7d9368c20c'	System	21 Aug 2020 22:49:13
User entered 'No (N)'	System	21 Aug 2020 22:49:13

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T17:49:10', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67940ba-d91a-4231-8c01-ee7d9368c20c'	System	21 Aug 2020 22:49:13
User entered '21 Aug 2020 17:49'	System	21 Aug 2020 22:49:13

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 17:32'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 20:02'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:14', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba2aa8de-9b9d-445c-a58e-bd5cfaa32a76'	System	22 Aug 2020 02:28:55
User entered 'None (0)'	System	22 Aug 2020 02:28:55

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:17', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba2aa8de-9b9d-445c-a58e-bd5cfaa32a76'	System	22 Aug 2020 02:28:55
User entered 'None (0)'	System	22 Aug 2020 02:28:55

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:19', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba2aa8de-9b9d-445c-a58e-bd5cfaa32a76'	System	22 Aug 2020 02:28:55
User entered 'None (0)'	System	22 Aug 2020 02:28:55

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:22', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba2aa8de-9b9d-445c-a58e-bd5cfaa32a76'	System	22 Aug 2020 02:28:55
User entered 'None (0)'	System	22 Aug 2020 02:28:55

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:25', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba2aa8de-9b9d-445c-a58e-bd5cfaa32a76'	System	22 Aug 2020 02:28:55
User entered 'None (0)'	System	22 Aug 2020 02:28:55

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:27', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba2aa8de-9b9d-445c-a58e-bd5cfaa32a76'	System	22 Aug 2020 02:28:55
User entered 'None (0)'	System	22 Aug 2020 02:28:55

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:31', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba2aa8de-9b9d-445c-a58e-bd5cfaa32a76'	System	22 Aug 2020 02:28:55
User entered 'No (N)'	System	22 Aug 2020 02:28:55

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-21T21:26:37', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba2aa8de-9b9d-445c-a58e-bd5cfaa32a76'	System	22 Aug 2020 02:28:55
User entered '21 Aug 2020 21:26'	System	22 Aug 2020 02:28:55

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '21 Aug 2020 20:57'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 2'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:37', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1d8aa895-7a18-4937-83fd-065c3ebd3c80'	System	22 Aug 2020 18:37:07
User entered 'None (0)'	System	22 Aug 2020 18:37:07

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:42', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1d8aa895-7a18-4937-83fd-065c3ebd3c80'	System	22 Aug 2020 18:37:07
User entered 'None (0)'	System	22 Aug 2020 18:37:07

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:45', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1d8aa895-7a18-4937-83fd-065c3ebd3c80'	System	22 Aug 2020 18:37:07
User entered 'None (0)'	System	22 Aug 2020 18:37:07

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:48', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1d8aa895-7a18-4937-83fd-065c3ebd3c80'	System	22 Aug 2020 18:37:07
User entered 'None (0)'	System	22 Aug 2020 18:37:07

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:51', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1d8aa895-7a18-4937-83fd-065c3ebd3c80'	System	22 Aug 2020 18:37:07
User entered 'None (0)'	System	22 Aug 2020 18:37:07

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:54', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1d8aa895-7a18-4937-83fd-065c3ebd3c80'	System	22 Aug 2020 18:37:07
User entered 'None (0)'	System	22 Aug 2020 18:37:07

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:36:58', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1d8aa895-7a18-4937-83fd-065c3ebd3c80'	System	22 Aug 2020 18:37:07
User entered 'No (N)'	System	22 Aug 2020 18:37:07

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-22T13:37:05', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1d8aa895-7a18-4937-83fd-065c3ebd3c80'	System	22 Aug 2020 18:37:07
User entered '22 Aug 2020 13:37'	System	22 Aug 2020 18:37:07

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 3'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:55', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a58701a6-5f3b-430a-871a-5bf08722f86c'	System	23 Aug 2020 17:39:20
User entered 'None (0)'	System	23 Aug 2020 17:39:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:38:57', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a58701a6-5f3b-430a-871a-5bf08722f86c'	System	23 Aug 2020 17:39:20
User entered 'None (0)'	System	23 Aug 2020 17:39:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:39:01', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a58701a6-5f3b-430a-871a-5bf08722f86c'	System	23 Aug 2020 17:39:20
User entered 'None (0)'	System	23 Aug 2020 17:39:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:39:05', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a58701a6-5f3b-430a-871a-5bf08722f86c'	System	23 Aug 2020 17:39:20
User entered 'None (0)'	System	23 Aug 2020 17:39:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:39:08', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a58701a6-5f3b-430a-871a-5bf08722f86c'	System	23 Aug 2020 17:39:20
User entered 'None (0)'	System	23 Aug 2020 17:39:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:39:10', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a58701a6-5f3b-430a-871a-5bf08722f86c'	System	23 Aug 2020 17:39:20
User entered 'None (0)'	System	23 Aug 2020 17:39:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:39:14', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a58701a6-5f3b-430a-871a-5bf08722f86c'	System	23 Aug 2020 17:39:20
User entered 'No (N)'	System	23 Aug 2020 17:39:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-23T12:39:18', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a58701a6-5f3b-430a-871a-5bf08722f86c'	System	23 Aug 2020 17:39:20
User entered '23 Aug 2020 12:39'	System	23 Aug 2020 17:39:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 4'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:30', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3f33c9ae-bb0a-40e7-831c-902ac567b40a'	System	24 Aug 2020 21:13:53
User entered 'None (0)'	System	24 Aug 2020 21:13:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:34', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3f33c9ae-bb0a-40e7-831c-902ac567b40a'	System	24 Aug 2020 21:13:53
User entered 'None (0)'	System	24 Aug 2020 21:13:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:37', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3f33c9ae-bb0a-40e7-831c-902ac567b40a'	System	24 Aug 2020 21:13:53
User entered 'None (0)'	System	24 Aug 2020 21:13:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:39', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3f33c9ae-bb0a-40e7-831c-902ac567b40a'	System	24 Aug 2020 21:13:53
User entered 'None (0)'	System	24 Aug 2020 21:13:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:41', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3f33c9ae-bb0a-40e7-831c-902ac567b40a'	System	24 Aug 2020 21:13:53
User entered 'None (0)'	System	24 Aug 2020 21:13:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:44', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3f33c9ae-bb0a-40e7-831c-902ac567b40a'	System	24 Aug 2020 21:13:53
User entered 'None (0)'	System	24 Aug 2020 21:13:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:47', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3f33c9ae-bb0a-40e7-831c-902ac567b40a'	System	24 Aug 2020 21:13:53
User entered 'No (N)'	System	24 Aug 2020 21:13:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-24T16:13:51', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3f33c9ae-bb0a-40e7-831c-902ac567b40a'	System	24 Aug 2020 21:13:53
User entered '24 Aug 2020 16:13'	System	24 Aug 2020 21:13:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 5'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:57', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab9667fe-94f0-45e0-8e4e-24203829d13a'	System	25 Aug 2020 17:55:20
User entered 'None (0)'	System	25 Aug 2020 17:55:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:54:59', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab9667fe-94f0-45e0-8e4e-24203829d13a'	System	25 Aug 2020 17:55:20
User entered 'None (0)'	System	25 Aug 2020 17:55:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:55:02', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab9667fe-94f0-45e0-8e4e-24203829d13a'	System	25 Aug 2020 17:55:20
User entered 'None (0)'	System	25 Aug 2020 17:55:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:55:04', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab9667fe-94f0-45e0-8e4e-24203829d13a'	System	25 Aug 2020 17:55:20
User entered 'None (0)'	System	25 Aug 2020 17:55:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:55:06', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab9667fe-94f0-45e0-8e4e-24203829d13a'	System	25 Aug 2020 17:55:20
User entered 'None (0)'	System	25 Aug 2020 17:55:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:55:08', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab9667fe-94f0-45e0-8e4e-24203829d13a'	System	25 Aug 2020 17:55:20
User entered 'None (0)'	System	25 Aug 2020 17:55:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:55:11', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab9667fe-94f0-45e0-8e4e-24203829d13a'	System	25 Aug 2020 17:55:20
User entered 'No (N)'	System	25 Aug 2020 17:55:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-25T12:55:15', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab9667fe-94f0-45e0-8e4e-24203829d13a'	System	25 Aug 2020 17:55:20
User entered '25 Aug 2020 12:55'	System	25 Aug 2020 17:55:20

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 6'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:08', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1493b08b-5b39-4ea4-beb5-537281afb64d'	System	26 Aug 2020 20:19:35
User entered 'None (0)'	System	26 Aug 2020 20:19:35

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:10', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1493b08b-5b39-4ea4-beb5-537281afb64d'	System	26 Aug 2020 20:19:35
User entered 'None (0)'	System	26 Aug 2020 20:19:35

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:12', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1493b08b-5b39-4ea4-beb5-537281afb64d'	System	26 Aug 2020 20:19:35
User entered 'None (0)'	System	26 Aug 2020 20:19:35

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:14', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1493b08b-5b39-4ea4-beb5-537281afb64d'	System	26 Aug 2020 20:19:35
User entered 'None (0)'	System	26 Aug 2020 20:19:35

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:15', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1493b08b-5b39-4ea4-beb5-537281afb64d'	System	26 Aug 2020 20:19:35
User entered 'None (0)'	System	26 Aug 2020 20:19:35

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:17', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1493b08b-5b39-4ea4-beb5-537281afb64d'	System	26 Aug 2020 20:19:35
User entered 'None (0)'	System	26 Aug 2020 20:19:35

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:20', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1493b08b-5b39-4ea4-beb5-537281afb64d'	System	26 Aug 2020 20:19:35
User entered 'No (N)'	System	26 Aug 2020 20:19:35

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-26T15:19:28', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '1493b08b-5b39-4ea4-beb5-537281afb64d'	System	26 Aug 2020 20:19:35
User entered '26 Aug 2020 15:19'	System	26 Aug 2020 20:19:35

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 7'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:47', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'c43ff8f7-a7d3-4450-8c9f-6581f22564b8'	System	27 Aug 2020 17:35:10
User entered 'None (0)'	System	27 Aug 2020 17:35:10

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:48', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'c43ff8f7-a7d3-4450-8c9f-6581f22564b8'	System	27 Aug 2020 17:35:10
User entered 'None (0)'	System	27 Aug 2020 17:35:10

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:50', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'c43ff8f7-a7d3-4450-8c9f-6581f22564b8'	System	27 Aug 2020 17:35:10
User entered 'None (0)'	System	27 Aug 2020 17:35:10

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:51', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'c43ff8f7-a7d3-4450-8c9f-6581f22564b8'	System	27 Aug 2020 17:35:10
User entered 'None (0)'	System	27 Aug 2020 17:35:10

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:53', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'c43ff8f7-a7d3-4450-8c9f-6581f22564b8'	System	27 Aug 2020 17:35:10
User entered 'None (0)'	System	27 Aug 2020 17:35:10

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:54', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'c43ff8f7-a7d3-4450-8c9f-6581f22564b8'	System	27 Aug 2020 17:35:10
User entered 'None (0)'	System	27 Aug 2020 17:35:10

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:34:59', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'c43ff8f7-a7d3-4450-8c9f-6581f22564b8'	System	27 Aug 2020 17:35:10
User entered 'No (N)'	System	27 Aug 2020 17:35:10

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-08-27T12:35:08', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'c43ff8f7-a7d3-4450-8c9f-6581f22564b8'	System	27 Aug 2020 17:35:10
User entered '27 Aug 2020 12:35'	System	27 Aug 2020 17:35:10

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 22:20:53

US3032305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	31 Aug 2020 21:08:49

US3032305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '28 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	31 Aug 2020 21:08:49
	(b) (4)	

US3032305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	31 Aug 2020 21:08:49

US3032305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	31 Aug 2020 21:08:49

US3032305

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	31 Aug 2020 21:08:52
	(b) (4)	

US3032305

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '1'	System	31 Aug 2020 21:08:52

US3032305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	08 Sep 2020 22:02:18

US3032305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '04 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	08 Sep 2020 22:02:18

US3032305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	08 Sep 2020 22:02:18

US3032305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	08 Sep 2020 22:02:18

US3032305

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	08 Sep 2020 22:02:22

US3032305

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'I'	System	08 Sep 2020 22:02:22

US3032305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:52:36

US3032305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	20 Nov 2020 20:48:21
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	20 Nov 2020 20:48:21
User entered '11 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	20 Nov 2020 20:48:21
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Signature has been broken.	System	20 Nov 2020 20:48:04
User entered '04 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	20 Nov 2020 20:48:04
User signature succeeded.	(b) (4)	
User entered '11 Sep 2020'	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 19:52:36

US3032305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:52:36

US3032305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:52:36

US3032305

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:52:41

US3032305

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'I'	System	11 Sep 2020 19:52:41

US3032305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:17

US3032305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:17

US3032305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:17

US3032305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'VISIT2'	System	22 Sep 2020 18:43:17

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '10:27'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '22 Sep 2020 10:27'	System	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '62'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'bpm'	System	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'breaths/min'	System	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '121'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'mmHg'	System	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '77'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'mmHg'	System	22 Sep 2020 18:47:52

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:48:02

US3032305

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:26

US3032305

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:26
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:54
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User closed query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, . Kindly update dosing discontinuation form accordingly. Thanks ' (Site from DM).		18 Nov 2020 03:41:02
Query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, . Kindly update dosing discontinuation form accordingly. Thanks ' answered with 'form has been updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 16:57:34
User opened query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, . Kindly update dosing discontinuation form accordingly. Thanks ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:01:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:08:52
User entered 'Confirmed COVID-19 (COVID)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:43:54

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:54
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:43:54

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:54
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:54
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:43:54

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:43:54
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:43:54

US3032305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:43:54

US3032305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:23
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:23
	(b) (4)	

US3032305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:09:22
User entered '11:00'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:23

US3032305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '22 Sep 2020 11:00'	System	22 Sep 2020 18:48:23

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '10:42'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '22 Sep 2020 10:42'	System	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered empty.	System	22 Sep 2020 18:48:35

US3032305

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 18:48:37

US3032305

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '1'	System	22 Sep 2020 18:48:37

US3032305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
DataPoint Un-verified.		26 Feb 2021 05:02:08
DataPoint Verified.		26 Feb 2021 05:01:56
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	20 Nov 2020 20:50:18

US3032305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
DataPoint Un-verified.		26 Feb 2021 05:02:11
DataPoint Verified.		26 Feb 2021 05:01:56
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	20 Nov 2020 20:50:18

US3032305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
DataPoint Un-verified.		26 Feb 2021 05:02:13
DataPoint Verified.		26 Feb 2021 05:01:56
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	20 Nov 2020 20:50:18

US3032305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
DataPoint Un-verified.		26 Feb 2021 05:02:15
DataPoint Verified.		26 Feb 2021 05:01:56
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	20 Nov 2020 20:50:18

US3032305

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 22:35:20

US3032305

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'I'	System	06 Oct 2020 22:35:20

US3032305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 22:36:34

US3032305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
Signature has been broken.	Linden DeBoer (b) (4)	20 Nov 2020 20:50:35
User entered '13 Oct 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	20 Nov 2020 20:50:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
User entered '6 Oct 2020'	Kelsey Kelley (b) (4)	06 Oct 2020 22:36:34

US3032305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 22:36:34

US3032305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 22:36:34
	(b) (4)	

US3032305

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:51:25
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 22:36:37

US3032305

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'I'	System	06 Oct 2020 22:36:37

US3032305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	13 Oct 2020 15:36:58

US3032305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
Signature has been broken.	Linden DeBoer (b) (4)	20 Nov 2020 20:50:51
User entered '06 Oct 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	20 Nov 2020 20:50:51
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User entered '13 Oct 2020'	Chelsie Nutsch (b) (4)	13 Oct 2020 15:36:58

US3032305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chelsie Nutsch (b) (4)	13 Oct 2020 15:36:58

US3032305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User entered empty.	Chelsie Nutsch (b) (4)	13 Oct 2020 15:36:58

US3032305

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	13 Oct 2020 15:37:03

US3032305

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'I'	System	13 Oct 2020 15:37:03

US3032305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:30:51
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:30:51
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:30:51
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'VISIT3'	System	19 Oct 2020 14:30:51

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '08:45'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '19 Oct 2020 08:45'	System	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '58'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'bpm'	System	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'breaths/min'	System	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '140'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'mmHg'	System	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '78'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'mmHg'	System	19 Oct 2020 14:31:17

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57

US3032305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57

US3032305

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:25
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:25
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:36
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:36
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '08:53'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:36

US3032305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered '19 Oct 2020 08:53'	System	19 Oct 2020 14:31:36

US3032305

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 14:31:47
	(b) (4)	

US3032305

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'I'	System	19 Oct 2020 14:31:47

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 64'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-10-25T14:25:11', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '5161332d-a544-4c48-bb06-082f5450b0d2'	System	25 Oct 2020 19:25:25
User entered 'No (N)'	System	25 Oct 2020 19:25:25

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-10-25T14:25:15', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '5161332d-a544-4c48-bb06-082f5450b0d2'	System	25 Oct 2020 19:25:25
User entered 'No (N)'	System	25 Oct 2020 19:25:25

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-10-25T14:25:23', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '5161332d-a544-4c48-bb06-082f5450b0d2'	System	25 Oct 2020 19:25:25
User entered '25 Oct 2020 14:25:23'	System	25 Oct 2020 19:25:25

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 71'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-10-28T08:07:21', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'e4f48af3-c1de-46b7-93b4-712e5c373100'	System	28 Oct 2020 13:07:34
User entered 'No (N)'	System	28 Oct 2020 13:07:34

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-10-28T08:07:26', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'e4f48af3-c1de-46b7-93b4-712e5c373100'	System	28 Oct 2020 13:07:34
User entered 'No (N)'	System	28 Oct 2020 13:07:34

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-10-28T08:07:32', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'e4f48af3-c1de-46b7-93b4-712e5c373100'	System	28 Oct 2020 13:07:34
User entered '28 Oct 2020 08:07:32'	System	28 Oct 2020 13:07:34

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 78'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-11-04T19:57:51', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '027c0869-4464-4c02-af4e-72008359578d'	System	05 Nov 2020 01:58:07
User entered 'No (N)'	System	05 Nov 2020 01:58:07

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-11-04T19:57:57', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '027c0869-4464-4c02-af4e-72008359578d'	System	05 Nov 2020 01:58:07
User entered 'No (N)'	System	05 Nov 2020 01:58:07

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-11-04T19:58:01', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '027c0869-4464-4c02-af4e-72008359578d' User entered '04 Nov 2020 19:58:01'	System	05 Nov 2020 01:58:07
	System	05 Nov 2020 01:58:07

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered 'Day 92'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-11-18T11:30:16', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '7fe5a863-d6fd-4ef1-85f9-4814af2b440c'	System	18 Nov 2020 17:30:31
User entered 'No (N)'	System	18 Nov 2020 17:30:31

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-11-18T11:30:22', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '7fe5a863-d6fd-4ef1-85f9-4814af2b440c'	System	18 Nov 2020 17:30:31
User entered 'No (N)'	System	18 Nov 2020 17:30:31

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-11-18T11:30:28', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '7fe5a863-d6fd-4ef1-85f9-4814af2b440c'	System	18 Nov 2020 17:30:31
User entered '18 Nov 2020 11:30:28'	System	18 Nov 2020 17:30:31

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 22:20:53

US3032305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:10:50
Data entry locked.	System	21 Aug 2020 22:20:53
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 22:20:53

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2020-11-25T19:02:17', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '30060389-41c4-4554-913b-529f2d223ae8'	System	26 Nov 2020 01:02:30
User entered 'No (N)'	System	26 Nov 2020 01:02:30

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2020-11-25T19:02:20', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '30060389-41c4-4554-913b-529f2d223ae8'	System	26 Nov 2020 01:02:30
User entered 'No (N)'	System	26 Nov 2020 01:02:30

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-11-25T19:02:27', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '30060389-41c4-4554-913b-529f2d223ae8'	System	26 Nov 2020 01:02:30
User entered '25 Nov 2020 19:02:27'	System	26 Nov 2020 01:02:30

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2020-11-29T18:57:34', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0c7bda62-6eba-4ca9-8d36-49041f17b84f'	System	30 Nov 2020 00:57:43
User entered 'No (N)'	System	30 Nov 2020 00:57:43

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2020-11-29T18:57:37', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0c7bda62-6eba-4ca9-8d36-49041f17b84f'	System	30 Nov 2020 00:57:43
User entered 'No (N)'	System	30 Nov 2020 00:57:43

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-11-29T18:57:41', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0c7bda62-6eba-4ca9-8d36-49041f17b84f'	System	30 Nov 2020 00:57:43
User entered '29 Nov 2020 18:57:41'	System	30 Nov 2020 00:57:43

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2020-12-06T15:42:39', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2d3d4a10-1781-416b-96e3-4dc128824a31'	System	06 Dec 2020 21:42:54
User entered 'No (N)'	System	06 Dec 2020 21:42:54

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2020-12-06T15:42:45', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2d3d4a10-1781-416b-96e3-4dc128824a31'	System	06 Dec 2020 21:42:54
User entered 'No (N)'	System	06 Dec 2020 21:42:54

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-12-06T15:42:50', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2d3d4a10-1781-416b-96e3-4dc128824a31'	System	06 Dec 2020 21:42:54
User entered '06 Dec 2020 15:42:50'	System	06 Dec 2020 21:42:54

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2020-12-13T07:40:38', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '51d14a2d-81b3-4a20-ad06-84d6d9e82bd8'	System	13 Dec 2020 13:40:49
User entered 'No (N)'	System	13 Dec 2020 13:40:49

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2020-12-13T07:40:42', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '51d14a2d-81b3-4a20-ad06-84d6d9e82bd8'	System	13 Dec 2020 13:40:49
User entered 'No (N)'	System	13 Dec 2020 13:40:49

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-12-13T07:40:46', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '51d14a2d-81b3-4a20-ad06-84d6d9e82bd8'	System	13 Dec 2020 13:40:49
User entered '13 Dec 2020 07:40:46'	System	13 Dec 2020 13:40:49

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2020-12-20T20:12:47', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '437b59c1-e147-4692-a648-f3bbc3b046c1'	System	21 Dec 2020 02:13:00
User entered 'No (N)'	System	21 Dec 2020 02:13:00

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2020-12-20T20:12:51', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '437b59c1-e147-4692-a648-f3bbc3b046c1'	System	21 Dec 2020 02:13:00
User entered 'No (N)'	System	21 Dec 2020 02:13:00

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-12-20T20:12:55', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '437b59c1-e147-4692-a648-f3bbc3b046c1'	System	21 Dec 2020 02:13:00
User entered '20 Dec 2020 20:12:55'	System	21 Dec 2020 02:13:00

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2020-12-27T21:03:42', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3ea50394-c69c-4b82-bfbc-f99db4a12862'	System	28 Dec 2020 03:03:52
User entered 'No (N)'	System	28 Dec 2020 03:03:52

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2020-12-27T21:03:45', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3ea50394-c69c-4b82-bfbc-f99db4a12862'	System	28 Dec 2020 03:03:52
User entered 'No (N)'	System	28 Dec 2020 03:03:52

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2020-12-27T21:03:49', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '3ea50394-c69c-4b82-bfbc-f99db4a12862'	System	28 Dec 2020 03:03:52
User entered '27 Dec 2020 21:03:49'	System	28 Dec 2020 03:03:52

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-01-03T14:38:03', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '33cc0d56-5368-483c-bb4e-cd4f55cfac22'	System	03 Jan 2021 20:38:14
User entered 'No (N)'	System	03 Jan 2021 20:38:14

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-01-03T14:38:06', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '33cc0d56-5368-483c-bb4e-cd4f55cfac22'	System	03 Jan 2021 20:38:14
User entered 'No (N)'	System	03 Jan 2021 20:38:14

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-01-03T14:38:11', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '33cc0d56-5368-483c-bb4e-cd4f55cfac22'	System	03 Jan 2021 20:38:14
User entered '03 Jan 2021 14:38:11'	System	03 Jan 2021 20:38:14

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-01-10T12:15:26', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'd883427b-28be-44ba-ae73-388dfa233ae8'	System	10 Jan 2021 18:15:33
User entered 'No (N)'	System	10 Jan 2021 18:15:33

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-01-10T12:15:29', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'd883427b-28be-44ba-ae73-388dfa233ae8'	System	10 Jan 2021 18:15:33
User entered 'No (N)'	System	10 Jan 2021 18:15:33

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-01-10T12:15:31', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'd883427b-28be-44ba-ae73-388dfa233ae8'	System	10 Jan 2021 18:15:33
User entered '10 Jan 2021 12:15:31'	System	10 Jan 2021 18:15:33

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-01-17T10:13:41', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67690ec-6b39-42fe-9720-d718bc95f0ae'	System	17 Jan 2021 16:13:52
User entered 'No (N)'	System	17 Jan 2021 16:13:52

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-01-17T10:13:44', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67690ec-6b39-42fe-9720-d718bc95f0ae'	System	17 Jan 2021 16:13:52
User entered 'No (N)'	System	17 Jan 2021 16:13:52

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-01-17T10:13:48', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'f67690ec-6b39-42fe-9720-d718bc95f0ae'	System	17 Jan 2021 16:13:52
User entered '17 Jan 2021 10:13:48'	System	17 Jan 2021 16:13:52

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-01-24T12:10:02', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'd0dbd431-b3cd-4dc1-9cf0-e29e5e2206fc'	System	24 Jan 2021 18:10:13
User entered 'No (N)'	System	24 Jan 2021 18:10:13

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-01-24T12:10:07', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'd0dbd431-b3cd-4dc1-9cf0-e29e5e2206fc'	System	24 Jan 2021 18:10:13
User entered 'No (N)'	System	24 Jan 2021 18:10:13

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-01-24T12:10:10', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'd0dbd431-b3cd-4dc1-9cf0-e29e5e2206fc' User entered '24 Jan 2021 12:10:10'	System	24 Jan 2021 18:10:13

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-01-31T07:50:41', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '7a7c3371-27c8-4891-9498-15d9e99e098c'	System	31 Jan 2021 13:51:04
User entered 'No (N)'	System	31 Jan 2021 13:51:04

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-01-31T07:50:45', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '7a7c3371-27c8-4891-9498-15d9e99e098c'	System	31 Jan 2021 13:51:04
User entered 'No (N)'	System	31 Jan 2021 13:51:04

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-01-31T07:50:50', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '7a7c3371-27c8-4891-9498-15d9e99e098c'	System	31 Jan 2021 13:51:04
User entered '31 Jan 2021 07:50:50'	System	31 Jan 2021 13:51:04

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-02-07T20:55:32', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '76056c34-545e-4087-bee6-ddc15a35580c'	System	08 Feb 2021 02:55:44
User entered 'No (N)'	System	08 Feb 2021 02:55:44

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-02-07T20:55:35', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '76056c34-545e-4087-bee6-ddc15a35580c'	System	08 Feb 2021 02:55:44
User entered 'No (N)'	System	08 Feb 2021 02:55:44

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-02-07T20:55:38', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '76056c34-545e-4087-bee6-ddc15a35580c'	System	08 Feb 2021 02:55:44
User entered '07 Feb 2021 20:55:38'	System	08 Feb 2021 02:55:44

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-02-14T18:12:14', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'cba4916f-dea2-43ac-a8cb-800124ff1998'	System	15 Feb 2021 00:14:41
User entered 'No (N)'	System	15 Feb 2021 00:14:41

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-02-14T18:12:17', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'cba4916f-dea2-43ac-a8cb-800124ff1998'	System	15 Feb 2021 00:14:41
User entered 'No (N)'	System	15 Feb 2021 00:14:41

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-02-14T18:12:28', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'cba4916f-dea2-43ac-a8cb-800124ff1998'	System	15 Feb 2021 00:14:41
User entered '14 Feb 2021 18:12:28'	System	15 Feb 2021 00:14:41

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-02-21T12:27:48', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab4ade17-0eec-44b4-88f9-722d4706d163'	System	21 Feb 2021 18:29:11
User entered 'No (N)'	System	21 Feb 2021 18:29:11

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-02-21T12:27:52', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab4ade17-0eec-44b4-88f9-722d4706d163'	System	21 Feb 2021 18:29:11
User entered 'No (N)'	System	21 Feb 2021 18:29:11

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-02-21T12:28:01', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ab4ade17-0eec-44b4-88f9-722d4706d163'	System	21 Feb 2021 18:29:11
User entered '21 Feb 2021 12:28:01'	System	21 Feb 2021 18:29:11

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-02-28T15:01:45-06:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '669b638b-ff9f-498d-b312-36387cdc3827'	System	28 Feb 2021 21:01:57
User entered 'No (N)'	System	28 Feb 2021 21:01:57

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-02-28T15:01:48-06:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '669b638b-ff9f-498d-b312-36387cdc3827'	System	28 Feb 2021 21:01:57
User entered 'No (N)'	System	28 Feb 2021 21:01:57

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-02-28T15:01:52-06:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '669b638b-ff9f-498d-b312-36387cdc3827' User entered '28 Feb 2021 15:01:52'	System	28 Feb 2021 21:01:57
	System	28 Feb 2021 21:01:57

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-03-07T11:58:27-06:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2f525b1b-3c2a-4e04-948e-6a3bab05de39'	System	07 Mar 2021 17:58:36
User entered 'No (N)'	System	07 Mar 2021 17:58:36

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-03-07T11:58:30-06:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2f525b1b-3c2a-4e04-948e-6a3bab05de39'	System	07 Mar 2021 17:58:36
User entered 'No (N)'	System	07 Mar 2021 17:58:36

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-03-07T11:58:33-06:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '2f525b1b-3c2a-4e04-948e-6a3bab05de39'	System	07 Mar 2021 17:58:36
User entered '07 Mar 2021 11:58:33'	System	07 Mar 2021 17:58:36

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-03-14T11:24:49-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a53c2122-f243-4c47-aebb-532fc64185c9'	System	14 Mar 2021 16:25:07
User entered 'No (N)'	System	14 Mar 2021 16:25:07

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-03-14T11:24:51-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a53c2122-f243-4c47-aebb-532fc64185c9'	System	14 Mar 2021 16:25:07
User entered 'No (N)'	System	14 Mar 2021 16:25:07

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-03-14T11:25:01-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'a53c2122-f243-4c47-aebb-532fc64185c9' User entered '14 Mar 2021 11:25:01'	System	14 Mar 2021 16:25:07
	System	14 Mar 2021 16:25:07

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-03-21T19:13:11-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0b9e4658-6254-4172-8c98-cbc77ef81005'	System	22 Mar 2021 00:13:22
User entered 'No (N)'	System	22 Mar 2021 00:13:22

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-03-21T19:13:14-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0b9e4658-6254-4172-8c98-cbc77ef81005'	System	22 Mar 2021 00:13:22
User entered 'No (N)'	System	22 Mar 2021 00:13:22

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-03-21T19:13:19-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '0b9e4658-6254-4172-8c98-cbc77ef81005'	System	22 Mar 2021 00:13:22
User entered '21 Mar 2021 19:13:19'	System	22 Mar 2021 00:13:22

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-04-05T15:32:28-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '26d09c96-a466-48a6-9c2d-5db84511a626'	System	05 Apr 2021 20:32:40
User entered 'No (N)'	System	05 Apr 2021 20:32:40

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-04-05T15:32:31-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '26d09c96-a466-48a6-9c2d-5db84511a626'	System	05 Apr 2021 20:32:40
User entered 'No (N)'	System	05 Apr 2021 20:32:40

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-04-05T15:32:36-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '26d09c96-a466-48a6-9c2d-5db84511a626'	System	05 Apr 2021 20:32:40
User entered '05 Apr 2021 15:32:36'	System	05 Apr 2021 20:32:40

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-04-11T07:35:23-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '4a123957-1600-4b2b-9ec9-4c772edbf663' User entered 'No (N)'	System	11 Apr 2021 12:35:31
	System	11 Apr 2021 12:35:31

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-04-11T07:35:25-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '4a123957-1600-4b2b-9ec9-4c772edbf663'	System	11 Apr 2021 12:35:31
User entered 'No (N)'	System	11 Apr 2021 12:35:31

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-04-11T07:35:28-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '4a123957-1600-4b2b-9ec9-4c772edbf663'	System	11 Apr 2021 12:35:31
User entered '11 Apr 2021 07:35:28'	System	11 Apr 2021 12:35:31

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-04-18T14:43:01-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '203c43f4-12e5-458f-b119-4e778f5c3fd8'	System	18 Apr 2021 19:43:11
User entered 'No (N)'	System	18 Apr 2021 19:43:11

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-04-18T14:43:04-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '203c43f4-12e5-458f-b119-4e778f5c3fd8'	System	18 Apr 2021 19:43:11
User entered 'No (N)'	System	18 Apr 2021 19:43:11

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-04-18T14:43:08-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '203c43f4-12e5-458f-b119-4e778f5c3fd8'	System	18 Apr 2021 19:43:11
User entered '18 Apr 2021 14:43:08'	System	18 Apr 2021 19:43:11

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-04-25T09:17:57-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b8265b1f-9acc-4154-951a-6d2c8f4aa625'	System	25 Apr 2021 14:18:05
User entered 'No (N)'	System	25 Apr 2021 14:18:05

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-04-25T09:18:01-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b8265b1f-9acc-4154-951a-6d2c8f4aa625'	System	25 Apr 2021 14:18:05
User entered 'No (N)'	System	25 Apr 2021 14:18:05

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-04-25T09:18:03-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'b8265b1f-9acc-4154-951a-6d2c8f4aa625'	System	25 Apr 2021 14:18:05
User entered '25 Apr 2021 09:18:03'	System	25 Apr 2021 14:18:05

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[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 (e4b8b8479a7f6043)', Time: '2021-05-02T18:26:47-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba663867-a256-4bc8-a716-234882e96c93'	System	02 May 2021 23:27:08
User entered 'No (N)'	System	02 May 2021 23:27:08

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

Have you been exposed to someone with 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 (e4b8b8479a7f6043)', Time: '2021-05-02T18:26:49-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba663867-a256-4bc8-a716-234882e96c93'	System	02 May 2021 23:27:08
User entered 'No (N)'	System	02 May 2021 23:27:08

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-05-02T18:27:03-05:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: 'ba663867-a256-4bc8-a716-234882e96c93'	System	02 May 2021 23:27:08
User entered '02 May 2021 18:27:03'	System	02 May 2021 23:27:08

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 01:05:34

US3032305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:34
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 01:05:34

US3032305

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:54:48

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 12:23:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-02-28T15:02:00-06:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '48e49a24-a27f-4c05-90ca-04e4e8ec4294'	System	28 Feb 2021 21:02:09
User entered 'No (N)'	System	28 Feb 2021 21:02:09

US3032305

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:54:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:23:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b8b8479a7f6043)', Time: '2021-02-28T15:02:05-06:00', User OID: 'PatientReportedOutcome (US3032305)', ODM File OID: '48e49a24-a27f-4c05-90ca-04e4e8ec4294'	System	28 Feb 2021 21:02:09
User entered '28 Feb 2021 15:02:05'	System	28 Feb 2021 21:02:09

US3032305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	16 Nov 2020 20:29:48

US3032305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User entered '16 Nov 2020'	Samantha Wieseler (b) (4)	16 Nov 2020 20:29:48

US3032305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	16 Nov 2020 20:29:48

US3032305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	16 Nov 2020 20:29:48
	(b) (4)	

US3032305

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	16 Nov 2020 20:29:52

US3032305

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:43:57
User entered 'I'	System	16 Nov 2020 20:29:52

US3032305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:08
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	18 Dec 2020 14:51:17

US3032305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:08
User entered '18 Dec 2020'	Samantha Wieseler (b) (4)	18 Dec 2020 14:51:17

US3032305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:08
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	18 Dec 2020 14:51:17

US3032305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:08
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Dec 2020 14:51:17

US3032305

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:08
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	18 Dec 2020 14:51:20

US3032305

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User entered 'I'	System	18 Dec 2020 14:51:20

US3032305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	16 Mar 2021 16:03:42

US3032305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered '18 Jan 2021'	Linden DeBoer (b) (4)	16 Mar 2021 16:03:42

US3032305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	16 Mar 2021 16:03:42

US3032305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:03:42

US3032305

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	16 Mar 2021 16:03:46

US3032305

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User entered 'I'	System	16 Mar 2021 16:03:46

US3032305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	16 Mar 2021 16:04:12

US3032305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered '17 Feb 2021'	Linden DeBoer (b) (4)	16 Mar 2021 16:04:12

US3032305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	16 Mar 2021 16:04:12

US3032305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:04:12

US3032305

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	16 Mar 2021 16:04:17

US3032305

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User entered '1'	System	16 Mar 2021 16:04:17

US3032305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:37:06

US3032305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '23 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:37:06
	(b) (4)	

US3032305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	23 Mar 2021 20:37:06

US3032305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User entered 'VISIT4'	System	23 Mar 2021 20:37:06

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).		28 Apr 2021 06:24:45
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'if vitals are charted in visit 4 in EDC they will not match source due to protocol not wanting vitals for Visit 4, therefore vitals will not be input for visit 4' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	20 Apr 2021 13:07:17
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:30:22
User closed query ' Per Sponsor review (RQ): Please note Visit 4 D209 and OL-D29 is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks' (Site from DM).		20 Apr 2021 09:30:22
Query ' Per Sponsor review (RQ): Please note Visit 4 D209 and OL-D29 is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks' answered with 'Per protocol visit 4 vitals not collected. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Apr 2021 20:03:23
User opened query ' Per Sponsor review (RQ): Please note Visit 4 D209 and OL-D29 is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:26:47

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Were vital signs assessed?

Audit	User	Time (GMT)
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you. ' (Site from DM). Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you.	(b) (4), (b) (6)	09 Apr 2021 11:26:47
' answered with 'Per protocol at time of this visit, vital signs are not collected as a part of visit 4' (Site from DM).	Kelsey Kelley (b) (4)	07 Apr 2021 19:54:17
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you.	(b) (4), (b) (6)	07 Apr 2021 09:51:29
' (Site from DM).		
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User entered empty.	System	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User entered empty.	System	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User entered empty.	System	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User entered empty.	System	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23
User entered empty.	System	30 Mar 2021 20:59:48

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23

US3032305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:23

US3032305

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:37:13

US3032305

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:37:13

US3032305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:37:27

US3032305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '23 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:37:27
	(b) (4)	

US3032305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '14:25'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:37:27

US3032305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User entered '23 Mar 2021 14:25'	System	23 Mar 2021 20:37:27

US3032305

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:37:29

US3032305

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:41:59
User entered 'I'	System	23 Mar 2021 20:37:29

US3032305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:05
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Apr 2021 19:00:35
	(b) (4)	

US3032305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:05
	(b) (4)	
User entered '20 Apr 2021'	Samantha Wieseler (b) (4)	20 Apr 2021 19:00:35
	(b) (4)	

US3032305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	20 Apr 2021 19:00:35

US3032305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:05
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	20 Apr 2021 19:00:35
	(b) (4)	

US3032305

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:05
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Apr 2021 19:00:40
	(b) (4)	

US3032305

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 19:00:40

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '10 Sep 2020'	Linden DeBoer (b) (4)	10 Sep 2020 20:00:47

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '13:00'	Linden DeBoer (b) (4)	10 Sep 2020 20:00:47

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:44
User entered '10 Sep 2020 13:00'	System	10 Sep 2020 20:00:47

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Safety Call (Safety Call)'	Linden DeBoer (b) (4)	10 Sep 2020 20:00:47

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:30:01
User closed query 'Per CDM: Please note that there is a "COVID-19 INFECTION" recorded on the AE page (AE#1); however, no diagnostic test is recorded. Kindly review and update this field as appropriate which will cause the COVID diagnostic test and Symptom log to populate and be completed. Review and update as appropriate, else provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 10:22:00
Query 'Per CDM: Please note that there is a "COVID-19 INFECTION" recorded on the AE page (AE#1); however, no diagnostic test is recorded. Kindly review and update this field as appropriate which will cause the COVID diagnostic test and Symptom log to populate and be completed. Review and update as appropriate, else provide clarification. ' answered with 'SUBJECT WAS ASYMPTOMATIC. SUBJECT CALLED SITE TO REPORT POSTIVE COVID TEST. SUBJECT STATED THE ONLY REASON SHE GOT TESTED WAS DUE TO EXPOSURE. SUBJECT GOT TEST OFF-SITE' (Site from DM).	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 21:35:31
User entered 'No (N)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 21:32:50
Signature has been broken.	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:11:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:11:16
User opened query 'Per CDM: Please note that there is a "COVID-19 INFECTION" recorded on the AE page (AE#1); however, no diagnostic test is recorded. Kindly review and update this field as appropriate which will cause the COVID diagnostic test and Symptom log to populate and be completed. Review and update as appropriate, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:49:59
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:08:52

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	10 Sep 2020 20:00:47

US3032305

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:54:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Sep 2020 20:00:52

US3032305

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:04:20

US3032305

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:04:20

US3032305

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[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 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	24 Feb 2021 01:04:20

US3032305

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'UNBLND_DECIDE'	System	24 Feb 2021 01:04:20

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '23 Feb 2021'	Kelsey Kelley (b) (4)	24 Feb 2021 01:04:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:35:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:04:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:40:23
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:35:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '23 Feb 2021'	Kelsey Kelley (b) (4)	24 Feb 2021 01:04:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'mRNA-1273 (mRNA-1273)'	Kelsey Kelley (b) (4)	24 Feb 2021 01:04:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'mRNA-1273 (mRNA-1273)'	Kelsey Kelley (b) (4)	24 Feb 2021 01:04:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Not Administered (NA)'	Kelsey Kelley (b) (4)	24 Feb 2021 01:04:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:04:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	24 Feb 2021 01:04:46

US3032305

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'I'	System	24 Feb 2021 01:04:46

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	24 Feb 2021 01:06:41
DataPoint set to visible.	System	24 Feb 2021 01:04:46

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	24 Feb 2021 01:06:41
DataPoint set to visible.	System	24 Feb 2021 01:04:46

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '23 Feb 2021'	Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '14:54'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '23 Feb 2021 14:54'	System	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41
	(b) (4)	

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '64'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'bpm'	System	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '18'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'breaths/min'	System	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '130'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'mmHg'	System	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'mmHg'	System	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:06:41

US3032305

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered empty.	System	24 Feb 2021 01:06:41
DataPoint set to visible.	System	24 Feb 2021 01:04:46

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59
	(b) (4)	

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '16:05'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '23 Feb 2021 16:05'	System	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59
	(b) (4)	

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '63'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'bpm'	System	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'breaths/min'	System	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '140'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'mmHg'	System	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '89'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:59

US3032305

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'mmHg'	System	24 Feb 2021 01:07:59

US3032305

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	24 Feb 2021 01:05:17

US3032305

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	24 Feb 2021 01:05:20
User entered '23 Feb 2021' reason for change: Data Entry Error	System	24 Feb 2021 01:05:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kelsey Kelley (b) (4)	24 Feb 2021 01:05:20
User entered '23 Feb 021' (non-conformant).	(b) (4)	24 Feb 2021 01:05:17
	Kelsey Kelley (b) (4)	24 Feb 2021 01:05:17
	(b) (4)	

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:07

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:07

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered empty.	Kelsey Kelley (b) (4)	24 Feb 2021 01:07:07

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'mRNA-1273'	System	24 Feb 2021 01:07:07
DataPoint set to visible.	System	24 Feb 2021 01:04:46

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:07:07

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '15:34'	Kelsey Kelley (b) (4)	24 Feb 2021 01:07:07

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '23 Feb 2021 15:34'	System	24 Feb 2021 01:07:07

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	24 Feb 2021 01:07:07

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'ONCE'	System	24 Feb 2021 01:07:07

US3032305

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 01:07:07

US3032305

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:04:59

US3032305

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:04:59

US3032305

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '14:25'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:04:59

US3032305

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '23 Feb 2021 14:25'	System	24 Feb 2021 01:04:59

US3032305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	24 Feb 2021 01:05:07

US3032305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:05:07

US3032305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '14:34'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:05:07

US3032305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:48

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered '23 Feb 2021 14:34'	System	24 Feb 2021 01:05:07

US3032305

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

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 01:05:10

US3032305

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

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:13:52
User entered 'I'	System	24 Feb 2021 01:05:10

US3032305

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:45
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:58:14

US3032305

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:45
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered '2 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:58:14

US3032305

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:45
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:58:14

US3032305

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:45
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:58:14

US3032305

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:45
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:58:19

US3032305

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:45
User entered 'I'	System	02 Mar 2021 20:58:19

US3032305

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:48

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:40:45
User entered 'I'	System	02 Mar 2021 20:58:19
DataPoint set to visible.	System	02 Mar 2021 20:58:19

US3032305

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 20:35:22

US3032305

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '23 Mar 2021'	Kelsey Kelley (b) (4)	23 Mar 2021 20:35:22

US3032305

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[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 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	23 Mar 2021 20:35:22

US3032305

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User entered 'OLD29'	System	23 Mar 2021 20:35:22

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '23 Mar 2021'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '14:15'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User entered '23 Mar 2021 14:15'	System	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '36.5' C	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '57'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User entered 'bpm'	System	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '18'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User entered 'breaths/min'	System	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '116'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User entered 'mmHg'	System	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered '69'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User entered 'mmHg'	System	23 Mar 2021 20:36:14

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23

US3032305

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23

US3032305

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:20

US3032305

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:20

US3032305

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:26

US3032305

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:26

US3032305

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:44:55
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 20:36:26

US3032305

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:49:23
User entered empty.	System	23 Mar 2021 20:36:26

US3032305

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:54:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:57:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	22 Sep 2020 18:44:01
User entered 'No (N)'	Linden DeBoer (b) (4)	10 Sep 2020 20:31:22

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Nov 2020 21:05:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:05:35
Data point term sent to Coder	System	12 Nov 2020 21:05:24
User closed query 'For consistency, please update to Covid 19 Infection.' (Site from System).	System	12 Nov 2020 21:05:11
Query 'For consistency, please update to Covid 19 Infection.' answered with 'data updated' (Site from System).	Linden DeBoer (b) (4)	12 Nov 2020 21:05:11
Coding entries removed.	Linden DeBoer (b) (4)	12 Nov 2020 21:05:03
Signature has been broken.	Linden DeBoer (b) (4)	12 Nov 2020 21:05:03
User entered 'COVID-19 infection' reason for change: Data Entry Error	Linden DeBoer (b) (4)	12 Nov 2020 21:05:03
User opened query 'For consistency, please update to Covid 19 Infection.' (Site from System).	Coder Import (b) (4)	07 Nov 2020 19:36:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:48:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:48:39
Data point term sent to Coder	System	22 Sep 2020 18:47:35
User entered 'sars-cov-2 infection'	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered '08 Sep 2020'	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	22 Sep 2020 18:54:54
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	22 Sep 2020 18:54:54
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	22 Sep 2020 18:47:11
User entered '08:00'	System	22 Sep 2020 18:47:11
	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:54:54
User entered '08 Sep 2020 08:00'	System	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered '08 Sep 2020'	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	22 Sep 2020 18:54:54
User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	22 Sep 2020 18:54:54
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	22 Sep 2020 18:54:54
User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System).	(b) (4)	22 Sep 2020 18:47:11
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	22 Sep 2020 18:47:11
User entered '08:00'	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:54:54
User entered '08 Sep 2020 08:00'	System	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
User closed query 'Per CDM : Please note as per CCGs AEs that started prior to first dose/ IP should be reported as NOT Applicable, the AE start date is after the first dose. Kindly check and clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 07:04:06
Query 'Per CDM : Please note as per CCGs AEs that started prior to first dose/ IP should be reported as NOT Applicable, the AE start date is after the first dose. Kindly check and clarify ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:44:57
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:44:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:44:49
User opened query 'Per CDM : Please note as per CCGs AEs that started prior to first dose/ IP should be reported as NOT Applicable, the AE start date is after the first dose. Kindly check and clarify ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:30:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:08:52
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 02:09:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 18:55:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 18:55:04
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:55:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:55:04
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 18:47:11
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:43:50
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	13 Oct 2020 14:44:49
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Linden DeBoer (b) (4)	13 Oct 2020 14:44:49
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User closed query 'Data is required. Please	System	22 Sep 2020 18:55:04
complete.' (Site from System).		
Query 'Data is required. Please complete.' answered	System	22 Sep 2020 18:55:04
by data change (Site from System).		
User entered 'Not Applicable (NOT APPLICABLE)'	Kelsey Kelley (b) (4)	22 Sep 2020 18:55:04
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please	System	22 Sep 2020 18:47:11
complete.' (Site from System).		
User entered empty.	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 05:33:56
User closed query 'Per DM CLR-RQ: Site's response noted. However, this information is not recorded on the Dosing Discontinuation eCRF page and/or End of Study/Study Discontinuation eCRF page. Please reconcile and update applicable eCRF pages as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:33:54
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'due to a COVID positive' (Site from System).	Linden DeBoer (b) (4)	12 Nov 2020 21:11:18
Query 'Per DM CLR-RQ: Site's response noted. However, this information is not recorded on the Dosing Discontinuation eCRF page and/or End of Study/Study Discontinuation eCRF page. Please reconcile and update applicable eCRF pages as appropriate. Otherwise, clarify.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4)	12 Nov 2020 21:06:11
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	12 Nov 2020 21:05:34
User opened query 'Per DM CLR-RQ: Site's response noted. However, this information is not recorded on the Dosing Discontinuation eCRF page and/or End of Study/Study Discontinuation eCRF page. Please reconcile and update applicable eCRF pages as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 22:54:51
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 22:54:51

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' answered with 'SUBJECT DID NOT RECEIVE DOSE 2 AT VISIT 2' (Site from DM).	Russell Herstein (b) (4) (b) (4)	21 Oct 2020 02:24:02
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	19 Oct 2020 05:46:27
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:08:52
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered 'I'	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Sep 2020 18:47:11
	(b) (4)	

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 18:47:11

US3032305

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 18:47:11

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:54:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:57:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:16:03

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 09:45:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 09:45:33
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	21 Sep 2020 17:11:48 21 Sep 2020 17:11:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Aug 2020 11:53:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 11:53:49
Data point term sent to Coder User entered 'metoprolol er'	System Kelsey Kelley (b) (4)	22 Aug 2020 00:18:23 22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:11:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 17:11:16
User entered 'medical history: supraventricular arrhythmia' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	21 Sep 2020 17:11:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 00:17:41
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:17:41
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 06:36:15
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:12:17
User entered '12.5' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:12:09
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:18:51
User entered '25 1/2'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	21 Sep 2020 17:12:09
	(b) (4)	
User entered 'tablet (TABLET)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:17:41
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'un Feb 2020'	Kelsey Kelley (b) (4)	22 Aug 2020 00:17:41
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:17:41
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 00:17:41

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:08:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:08:52
Data point term sent to Coder	System	21 Sep 2020 17:07:40
User entered 'LEVOTHYROXINE' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	21 Sep 2020 17:07:38
Coding entries removed.	Kelsey Kelley (b) (4)	21 Sep 2020 17:07:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 12:03:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 12:03:34
Data point term sent to Coder	System	22 Aug 2020 00:18:24
User entered 'levothyroxinw'	Kelsey Kelley (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'MEDICAL HISTORY: HYPOTHYROIDISM' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	21 Sep 2020 17:07:30
User entered 'medical history: medical history: hypothyroidism'	Kelsey Kelley (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '112'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:07:30
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	21 Sep 2020 17:07:30
	(b) (4)	
User entered 'mcg'	Kelsey Kelley (b) (4)	22 Aug 2020 00:18:23
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2011'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 00:18:23

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Sep 2020 17:13:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:13:43
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4) (b) (4) (b) (4)	21 Sep 2020 17:12:50 21 Sep 2020 17:12:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 00:20:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 00:20:29
Data point term sent to Coder User entered 'atorvastatin'	System Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:19:24 22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:12:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 17:12:40
User entered 'medical history: hypercholesterolemia' reason for change: New Information	Kelsey Kelley (b) (4)	21 Sep 2020 17:12:40
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 00:18:48
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:18:48
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '10'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:18:48
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2017'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 00:18:48

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 16:52:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 16:52:44
Data point term sent to Coder	System	16 Nov 2020 16:51:57
Coding entries removed.	Kelsey Kelley (b) (4)	16 Nov 2020 16:51:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:06:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:06:29
Data point term sent to Coder	System	09 Oct 2020 16:06:01
Coding entries removed.	Linden DeBoer (b) (4)	09 Oct 2020 16:05:12
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:14:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:14:49
Data point term sent to Coder	System	21 Sep 2020 17:13:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Kelsey Kelley (b) (4)	21 Sep 2020 17:13:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 00:20:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 00:20:29
Data point term sent to Coder	System	22 Aug 2020 00:19:24
User entered 'eliquis'	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:24
User closed query 'Per DM CLR: Prophylaxis = NO. However, Indication reflects as a Prophylaxis. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 06:06:39
Query 'Per DM CLR: Prophylaxis = NO. However, Indication reflects as a Prophylaxis. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 16:50:42
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 16:50:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 16:50:30
User opened query 'Per DM CLR: Prophylaxis = NO. However, Indication reflects as a Prophylaxis. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:05:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:24
Signature has been broken.	Kelsey Kelley (b) (4)	16 Nov 2020 16:51:00
User entered 'MEDICAL HISTORY: PULMONARY EMBOLISM PROPHYLAXIS' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 16:51:00
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:08:37
Signature has been broken.	Linden DeBoer (b) (4)	09 Oct 2020 16:05:12
User entered 'MEDICAL HISTORY: PULMONARY EMBOLISM Prophylaxes' reason for change: Data Entry Error	Linden DeBoer (b) (4)	09 Oct 2020 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:13:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 17:13:13
User entered 'medical history: pulmonary embolism' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	21 Sep 2020 17:13:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 00:19:22
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '5'	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un Feb 2020'	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:54:13
Signature has been broken.	Samantha Wieseler (b) (4)	20 Jan 2021 00:08:58
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	20 Jan 2021 00:08:58
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH has resolved (BILATERAL PULMONARY EMBOLISM, FEB 2020 to APR 2020). If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:38:44
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH has resolved (BILATERAL PULMONARY EMBOLISM, FEB 2020 to APR 2020). If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'PE Prophylaxes ' (Site from DM).	Linden DeBoer (b) (4)	09 Oct 2020 16:04:53
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH has resolved (BILATERAL PULMONARY EMBOLISM, FEB 2020 to APR 2020). If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:53:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:54:13
Signature has been broken.	Samantha Wieseler (b) (4)	20 Jan 2021 00:08:58
User entered '26 Aug 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	20 Jan 2021 00:08:58
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User entered '2'	System	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User entered '1'	System	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:06:20
User entered '804 (804)'	System	22 Aug 2020 00:19:22

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Aug 2020 05:09:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 05:09:24
Data point term sent to Coder	System	22 Aug 2020 00:20:25
User entered 'ropinirole'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'medical history: restless leg syndrome'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '1'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:20:17
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'once daily (QD)' reason for change:	Kelsey Kelley (b) (4)	21 Sep 2020 17:13:45
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:20:17
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 11:57:11
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:13:53
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:13:45
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:17:48
User entered 'every hour'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:20:17
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:13:45
User entered empty.	System	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:13:45
User entered empty.	System	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:13:45
User entered empty.	System	22 Aug 2020 00:20:17

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Aug 2020 06:13:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 06:13:27
Data point term sent to Coder	System	22 Aug 2020 00:21:25
User entered 'calcium + vitamin d'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'medical history: osteopenia'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this combination medication. Please correct the dose and unit or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:13:15
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:24
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this combination medication. Please correct the dose and unit or provide explanation for alternate dosage.' answered with 'DATA UPDATED' (Site from DM). Signature has been broken.	Russell Herstein (b) (4)	19 Nov 2020 21:38:17
	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 21:37:50
	(b) (4)	
User entered '600/400' reason for change: Data Entry Error	Russell Herstein (b) (4)	19 Nov 2020 21:37:50
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this combination medication. Please correct the dose and unit or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:07:19
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:24:46
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	30 Sep 2020 22:24:19
	(b) (4)	
User entered '1000/200' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	30 Sep 2020 22:23:59
	(b) (4)	
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:16:31
User entered '600'	Kelsey Kelley (b) (4)	22 Aug 2020 00:20:45
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:24
	(b) (4)	
Signature has been broken.	Russell Herstein (b) (4)	19 Nov 2020 21:37:50
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Russell Herstein (b) (4)	19 Nov 2020 21:37:50
Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:20:45
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:24
	(b) (4)	
Signature has been broken.	Russell Herstein (b) (4)	19 Nov 2020 21:37:50
	(b) (4)	
User entered 'MG/IU' reason for change: Data Entry Error	Russell Herstein (b) (4)	19 Nov 2020 21:37:50
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 00:20:45
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2016'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 00:20:45

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User closed query 'Per DM CLR: Please review to record the medication given for this condition. Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 08:24:59
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) (b) (4)	30 Sep 2020 22:27:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 22:27:39
Data point term sent to Coder	System	30 Sep 2020 22:26:31
User entered 'Omeprazole' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:26:00
Query 'Per DM CLR: Please review to record the medication given for this condition. Reconcile and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:25:30
Data point term sent to Coder	System	30 Sep 2020 22:25:26
User closed query 'DM-Coding: This event is not appropriate to be reported as a Concomitant Medication. Kindly move this term Medical History to another appropriate field. Please update this term in accordance with your answer.' (Site from System).	System	30 Sep 2020 22:25:24
Query 'DM-Coding: This event is not appropriate to be reported as a Concomitant Medication. Kindly move this term Medical History to another appropriate field. Please update this term in accordance with your answer.' answered with 'updated' (Site from System).	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:25:24
User opened query 'Per DM CLR: Please review to record the medication given for this condition. Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:15:31

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'DM-Coding: This event is not appropriate to be reported as a Concomitant Medication. Kindly move this term Medical History to another appropriate field. Please update this term in accordance with your answer.' (Site from System). Data point term sent to Coder	Coder Import (b) (4)	24 Aug 2020 09:32:27
User entered 'acid reflux'	System Kelsey Kelley (b) (4)	22 Aug 2020 00:21:27 22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'medical history: acid reflux'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '20'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:21:19
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 00:21:19

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

Name of Medication

Audit	User	Time (GMT)
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)	19 Nov 2020 20:15:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 20:15:01
Data point term sent to Coder Coding entries removed.	System Russell Herstein (b) (4)	18 Nov 2020 21:43:14 18 Nov 2020 21:43:11
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)	09 Oct 2020 17:47:34
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 17:47:34
Data point term sent to Coder Coding entries removed.	System Linden DeBoer (b) (4)	09 Oct 2020 16:07:10 09 Oct 2020 16:06:11
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
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)	21 Sep 2020 21:54:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 21:54:54
Data point term sent to Coder User entered 'apixaban'	System Kelsey Kelley (b) (4)	21 Sep 2020 17:17:04 21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:24
User closed query 'Per DM CLR: Prophylaxis = NO. However, Indication reflects as a Prophylaxis. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 06:06:50
Query 'Per DM CLR: Prophylaxis = NO. However, Indication reflects as a Prophylaxis. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' answered with 'updated data' (Site from DM).	Russell Herstein (b) (4) (b) (4)	18 Nov 2020 21:43:23
Signature has been broken.	Russell Herstein (b) (4) (b) (4)	18 Nov 2020 21:43:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	18 Nov 2020 21:43:11
User opened query 'Per DM CLR: Prophylaxis = NO. However, Indication reflects as a Prophylaxis. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:07:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:24
Signature has been broken.	(b) (4)	
	Russell Herstein (b) (4)	18 Nov 2020 21:43:11
	(b) (4)	
User entered 'PULMONARY EMBOLISM PROPHYLAXIS' reason for change: Data Entry Error	Russell Herstein (b) (4)	18 Nov 2020 21:43:11
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no Med History that matches this Con Med indication during this time frame (26AUG2020). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as applicable. Note, Med History of BILATERAL PULMONARY EMBOLISM has already resolved since APR2020.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 04:28:32
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:08:37
	(b) (4)	
Query 'Per DM CLR: Please note that there is no Med History that matches this Con Med indication during this time frame (26AUG2020). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as applicable. Note, Med History of BILATERAL PULMONARY EMBOLISM has already resolved since APR2020.' answered with 'used for Prophylaxes ' (Site from DM).	Linden DeBoer (b) (4)	09 Oct 2020 16:06:21
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	09 Oct 2020 16:06:11
	(b) (4)	
User entered 'MEDICAL HISTORY: PULMONARY EMBOLISM Prophylaxes' reason for change: Data Entry Error	Linden DeBoer (b) (4)	09 Oct 2020 16:06:11
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Med History that matches this Con Med indication during this time frame (26AUG2020). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as applicable. Note, Med History of BILATERAL PULMONARY EMBOLISM has already resolved since APR2020.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:59:09
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'medical history: pulmonary embolism'	Kelsey Kelley (b) (4)	21 Sep 2020 17:16:43
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

1667 of 1704

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '2.5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:16:43
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:16:43
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4 ELIQUIS (UN FEB 2020-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:57:20
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4 ELIQUIS (UN FEB 2020-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	20 Jan 2021 00:09:09
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4 ELIQUIS (UN FEB 2020-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:53:26
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '26 Aug 2020'	Kelsey Kelley (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:16:43
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:08:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:16:43

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
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)	19 Oct 2020 15:02:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 15:02:41
Data point term sent to Coder	System	19 Oct 2020 15:01:47
User entered 'seasonal influenza vaccine'	Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	19 Oct 2020 15:01:33
User entered 'No (N)'	Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'seasonal influenza prophylaxis'	Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '0.5'	Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'mL (mL)'	Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '10 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '0'	Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered '10 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51
	(b) (4)	

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:04:27
User entered 'No (N)'	Kelsey Kelley (b) (4)	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User entered empty.	System	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User entered empty.	System	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:54:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:37:15
User entered empty.	System	19 Oct 2020 15:00:51

US3032305

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:54:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:08:52
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 00:31:10
	(b) (4)	

US3032305

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:54:48

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:18
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User entered '08 Sep 2020'	(b) (4)	
	Linden DeBoer (b) (4)	12 Nov 2020 21:05:34
	(b) (4)	

US3032305

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:54:48

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:18
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4) Linden DeBoer (b) (4)	12 Nov 2020 21:05:34
	(b) (4)	

US3032305

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:54:48

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:18
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:53:29
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4)	12 Nov 2020 21:12:03
User entered empty; reason for change Data Entry Error	System	12 Nov 2020 21:12:03
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	Linden DeBoer (b) (4)	12 Nov 2020 21:12:03
User entered 'subject was COVID positive' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 21:11:49
User entered empty.	System	12 Nov 2020 21:11:49
	Linden DeBoer (b) (4)	12 Nov 2020 21:11:49
	(b) (4)	12 Nov 2020 21:11:49
	Linden DeBoer (b) (4)	12 Nov 2020 21:05:34
	(b) (4)	12 Nov 2020 21:05:34