

US3272031 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:55:18

All time stamps listed in this document are displayed in GMT

US3272031

Form: Participant Creation

Generated On: 26 Nov 2020 10:55:18

[Participant ID](#)

US3272031

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

US3272031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
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

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

Date of Informed Consent (<i>dd MMM yyyy</i>)	01 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input 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

US3272031

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:55:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3272031

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:55:18

Were any significant conditions reported?

Yes ☒

No ☐

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

Condition	TOTAL RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	06 AUG 2019
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)	06 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

Condition	TOTAL LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN OCT 2016
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 OCT 2016
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2016
Start Year (derived)	2016
Stop Month and Year (derived)	OCT 2016
Stop Year (derived)	2016

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

Condition	TOTAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

Condition	LICHEN SCLEROSUS BILATERAL LOWER EXTREMITIES
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)	

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

Condition	ORAL HERPES SIMPLEX 1
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

Condition	EMPHYSEMA
Start date (dd MMM yyyy)	15 MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

Condition	GRAVES DISEASE
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

Condition	BILATERAL KNEE PAIN
Start date (dd MMM yyyy)	UN UNK 2014
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)	06 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

Condition	TYPE 2 DIABETES
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)	

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

Condition	MAMMOGRAM
Start date (dd MMM yyyy)	28 JUL 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)	28 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:46 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 12:46
Height (<i>xxx.x</i>)	175.0 cm
Weight (<i>xxx.x</i>)	123.0 kg
BMI (<i>xxx.x</i>)	40.16327 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272031

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 AUG 2020

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

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

Date of assessment (<i>dd MMM yyyy</i>)	1 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2002
Date of last menstruation unknown	False

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

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 BIKING, GROCERY SHOPPING, SOCIALIZATION WITH FRIENDS.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

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	

US3272031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

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

What was the participant's randomization number? 184340

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 ☒

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:18

Height	ND - Not Done
Weight	ND - Not Done

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

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)	01 AUG 2020
Time of assessment (00:00-23:59)	12:46 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 12:46
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

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)	01 AUG 2020
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 14:39
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3272031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 AUG 2020

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

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	01 AUG 2020
What was the treatment time? (00:00-23:59)	14:09 (24 HR)
Treatment Date and Time (derived)	01 AUG 2020 14:09
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3272031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	01 AUG 2020
Collection time (<i>00:00-23:59</i>)	13:26 (24 HR)
Collection date and time (derived)	01 AUG 2020 13:26

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:18

Collection date (<i>dd MMM yyyy</i>)			01 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:11	01 AUG 2020 13:11
Nasopharyngeal Swab 2	No		

US3272031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

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

01 AUG 2020 14:52

PC Open Date & Time

01 AUG 2020 14:29

PC Close Date & Time

01 AUG 2020 16:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	01 AUG 2020 18:02
PC Open Date & Time	01 AUG 2020 17:54
PC Close Date & Time	02 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:18

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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 16:04

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

03 AUG 2020 15:01

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 15:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:55:18

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 14:46

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:55:18

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 13:53

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:55:18

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 14:17

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 14:53

PC Open Date & Time

01 AUG 2020 14:29

PC Close Date & Time

01 AUG 2020 16:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 18:02

PC Open Date & Time

01 AUG 2020 17:54

PC Close Date & Time

02 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 16:05

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 15:02

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 15:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 14:47

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 13:53

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 14:17

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 14:54
PC Open Date & Time	01 AUG 2020 14:29
PC Close Date & Time	01 AUG 2020 16:59

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 18:03
PC Open Date & Time	01 AUG 2020 17:54
PC Close Date & Time	02 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

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 ☒

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

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 ☒

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

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 ☒

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 15:31
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

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 ☒

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 14:48
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

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 ☒

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 13:54
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

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 ☒

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 14:18
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3272031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

Was Contact Attempted?

Yes ☒

No ☐

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

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

Was Contact Attempted?

Yes ☒

No ☐

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

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

Was Contact Attempted?

Yes ☒

No ☐

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

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:10
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3272031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

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

PATIENT HAS BREAST CANCER AND WILL BE UNDERGOING RADIATION

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? _____

US3272031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	01 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:35 (24 HR)
Collection date and time (derived)	01 SEP 2020 12:35

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:18

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:29	01 SEP 2020 12:29
Nasopharyngeal Swab 2	No		

US3272031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

Was Contact Attempted?

Yes ☒

No ☐

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

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

Was Contact Attempted?

Yes ☒

No ☐

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

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

Was Contact Attempted?

Yes ☒

No ☐

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

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT3

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:56 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:56
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	29 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:06 (24 HR)
Collection date and time (derived)	29 SEP 2020 12:06

US3272031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 OCT 2020 09:21:28

Patient Cloud Open Date & Time

01 OCT 2020 00:01

Patient Cloud Close Date & Time

05 OCT 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

12 OCT 2020 10:44:23

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 07:33:20

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

29 OCT 2020 07:14:17

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 10:16:16

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 07:37:22

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2020 00:01
Patient Cloud Close Date & Time	02 OCT 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

19 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 <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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

19 NOV 2020 07:17:10

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

23 NOV 2020 07:38:59

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 <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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 <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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 <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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 236

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐
Yes ☐

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	09 JUL 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐
Yes ☐

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐
Yes ☐

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	22 APR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	17 JUN 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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="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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	30 SEP 2022 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

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"/>

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	07 OCT 2022 23:59

US3272031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

Was Contact Attempted?

Yes ☒

No ☐

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

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272031

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:55:18

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"/>

US3272031

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:55:18

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3272031

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:55:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

AEID	USA-US070-2020-MRNA-1273-P30 1000001
Adverse event	STAGE 1 LEFT BREAST CANCER
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)	17 AUG 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)	27 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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	

v6.020 DTW (1102)

320 of 1778

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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	

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

<hr/>		SUBJECT DIAGNOSED WITH STAGE 1 BREAST CANCER. SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. BIOPSY PERFORMED ON 05 AUG 2020. SUBJECT SCHEDULED TO HAVE A LUMPECTOMY ON 26 AUG 2020. PATHOLOGY OF BOTH MASSES REVELED INVASIVE DUCTAL CARCINOMA, GRADE 2, ER/PR 100% POSITIVE, HER-2 NEGATIVE, PERINEURAL INVASION PRESENT AND DCIS.
<hr/>		
Serious Adverse Event Derived (CSA Programming Field Only)	1	
Medically Attended AE Derived (CSA Programming Field Only)	1	
Admitted to ICU Derived (CSA Programming Field Only)		
<hr/>		

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:55:18

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

Yes ☒

No ☐

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

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GRAVES DISEASE
Dose per administration	175
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

	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 2006	
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"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	LOSARTAN POTASSIUM/HYDROCHLOROTH IAZIDE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERTENSION
Dose per administration	125/100
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

	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 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	METFORMIN ER
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TYPE 2 DIABETES
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	BENADRYL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SEASONAL ALLERGIES
Dose per administration	25
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
<hr/>		
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"/>	

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

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 2013
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"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	L-LYSINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HERPES SIMPLEX 1
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

	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 1975
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"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	20
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

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

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	VITAMIN D3
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	50
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		15 JUL 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	VITAMIN B
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	250
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		15 JUL 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	SYMBICORT
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	EMPHYSEMA
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input checked="" type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	CLOBETASOL PROPIONATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LICHEN SCLEROSES
Dose per administration	NA
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	NA
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	TWICE A WEEK
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	BLACK COHOSH
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	VASOMOTOR SYMPTOMS
Dose per administration	540
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

	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"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	1
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input checked="" type="radio"/>

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

	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)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:55:18

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:55:18

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
26 AUG 2020	LUMPECTOMY	Adverse Event	
5 AUG 2020	BIOPSY ON LEFT BREAST	Diagnostic	

US3272031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:55:18

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3272031

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:55:18

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 ☐

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

SAEID	USA-US070-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:18

SAEID	USA-US070-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/AUG/2020 13:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:55:18

SAEID	USA-US070-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	27/AUG/2020 12:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:55:18

SAEID	USA-US070-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/SEP/2020 21:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:55:18

SAEID	USA-US070-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/SEP/2020 09:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3272031 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272031

Form: Participant Creation

Generated On: 26 Nov 2020 10:55:18

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3272031'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	01 Aug 2020 18:39:13

US3272031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:38
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:14:54

US3272031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:38
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:39:14

US3272031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:38
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:14:54

US3272031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Aug 2020 19:14:54

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:39:15

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '67'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

Sex

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm the patients sex as male (given MH of postmenopausal, total hysterectomy, etc).' ' (Site from Safety).</td <td>(b) (4), (b) (6)</td> <td>27 Aug 2020 16:22:55</td>	(b) (4), (b) (6)	27 Aug 2020 16:22:55
Query 'PV Query: Please confirm the patients sex as male (given MH of postmenopausal, total hysterectomy, etc).' ' answered with 'updated' (Site from Safety).</td <td>Kayla Flege (b) (4)</td> <td>27 Aug 2020 13:19:52</td>	Kayla Flege (b) (4)	27 Aug 2020 13:19:52
DataPoint Un-verified.	(b) (4)	
User entered 'Female (F)' reason for change: Data Entry Error	Kayla Flege (b) (4)	27 Aug 2020 13:19:46
User opened query 'PV Query: Please confirm the patients sex as male (given MH of postmenopausal, total hysterectomy, etc).' ' (Site from Safety).</td <td>(b) (4), (b) (6)</td> <td>25 Aug 2020 13:26:01</td>	(b) (4), (b) (6)	25 Aug 2020 13:26:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered 'Male (M)'	Kayla Flege (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:18

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Aug 2020 18:39:14

US3272031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:56
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:55:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:08
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:13

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:10:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:10:09
Data point term sent to Coder	System	01 Aug 2020 20:20:15
User entered 'Total right knee replacement'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '06 Aug 2019'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '06 Aug 2019'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2019'	System	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2019'	System	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:10:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:10:08
Data point term sent to Coder	System	01 Aug 2020 20:21:15
User entered 'total left knee replacement'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un Oct 2016'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un Oct 2016'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Oct 2016'	System	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2016'	System	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Oct 2016'	System	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2016'	System	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:23:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:23:10
Data point term sent to Coder	System	01 Aug 2020 20:22:16
User entered 'Cholecystectomy'	Kayla Flege (b) (4)	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:23:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:23:10
Data point term sent to Coder	System	01 Aug 2020 20:22:16
User entered 'Cholecystitis'	Kayla Flege (b) (4)	01 Aug 2020 20:22:04
	(b) (4)	

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:24:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:24:10
Data point term sent to Coder	System	01 Aug 2020 20:23:17
User entered 'Total Hysterectomy'	Kayla Flege (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2002'	System	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2002'	System	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:24:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:24:10
Data point term sent to Coder	System	01 Aug 2020 20:23:16
User entered 'Menorrhagia'	Kayla Flege (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:02:55
User entered 'UN Apr 2002' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:02:33
User entered 'un UNK 2002'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	17 Nov 2020 17:02:55
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	17 Nov 2020 17:02:33
User entered 'un UNK 2002'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	17 Nov 2020 17:02:55
User entered 'Apr 2002'	System	17 Nov 2020 17:02:33
User entered 'Jan 2002'	System	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2002'	System	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2002'	System	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of LICHEN SCLEROSUS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:01:42
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Papulosquamous conditions, PT: Lichen sclerosus, LLT: Lichen sclerosus - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 07:28:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 07:28:17
Data point term sent to Coder	System	01 Oct 2020 21:25:36
Query 'Per DM CLR: Please specify the location of LICHEN SCLEROSUS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	01 Oct 2020 21:24:54
Coding entries removed.	Kayla Flege (b) (4)	01 Oct 2020 21:24:49
User entered 'LICHEN SCLEROSUS Bilateral Lower extremities' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Oct 2020 21:24:49
User opened query 'Per DM CLR: Please specify the location of LICHEN SCLEROSUS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:56:50
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Papulosquamous conditions, PT: Lichen sclerosus, LLT: Lichen sclerosus - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:24:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:24:10
Data point term sent to Coder	System	01 Aug 2020 20:23:16
User entered 'Lichen Sclerosus'	Kayla Flege (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2018'	System	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Herpes simplex oral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:27:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:27:52
User closed query 'Per DM CLR: Please specify the location of HERPES SIMPLEX 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:03:24
Data point term sent to Coder	System	01 Oct 2020 21:25:36
Query 'Per DM CLR: Please specify the location of HERPES SIMPLEX 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:25:23
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:25:09
User entered 'Oral HERPES SIMPLEX 1' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:25:09
User opened query 'Per DM CLR: Please specify the location of HERPES SIMPLEX 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:57:07
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 09:51:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 09:51:08
Data point term sent to Coder	System	01 Aug 2020 20:25:17
User entered 'Herpes Simplex 1'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 1975'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '1975'	System	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
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: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:26:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:26:10
Data point term sent to Coder	System	01 Aug 2020 20:25:17
User entered 'Gastroesophageal Reflux Disease'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location and/or type of EMPHYSEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:05:01
Query 'Per DM CLR: Please specify the location and/or type of EMPHYSEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Emphysema is located in lungs' (Site from DM).	Kayla Flege (b) (4)	01 Oct 2020 21:22:38
User opened query 'Per DM CLR: Please specify the location and/or type of EMPHYSEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:57:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:27:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:27:11
Data point term sent to Coder	System	01 Aug 2020 20:26:18
User entered 'Emphysema'	Kayla Flege (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '15 May 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'May 2020'	System	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Basedow's disease, LLT: Graves' disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 09:35:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 09:35:59
Data point term sent to Coder	System	01 Aug 2020 20:26:18
User entered 'Graves Disease'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2006'	System	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:07:36
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	01 Oct 2020 21:28:47
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:58:02
User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	01 Aug 2020 20:27:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Aug 2020 20:27:11
Data point term sent to Coder	System	01 Aug 2020 20:26:18
User entered 'Hypertension'	Kayla Flege (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:28:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:28:11
Data point term sent to Coder	System	01 Aug 2020 20:27:19
User entered 'Seasonal Allergies'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2000'	System	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:28:12
Data point term sent to Coder	System	01 Aug 2020 20:27:20
User entered 'Bilateral Knee Pain'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '06 Aug 2019'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2014'	System	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2019'	System	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:09:11
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	01 Oct 2020 21:29:05
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:58:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:29:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:29:12
Data point term sent to Coder	System	01 Aug 2020 20:28:20
User entered 'Type 2 Diabetes'	Kayla Flege (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2018'	System	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:44:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:44:39
Data point term sent to Coder	System	06 Sep 2020 18:43:03
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:42:25
User entered 'Severe OBESITY' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:42:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:29:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:29:12
Data point term sent to Coder	System	01 Aug 2020 20:28:21
User entered 'Obesity'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:04:35
User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 13:26:08
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22. Thank you' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:42:30
User entered 'un UNK 2010' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:42:25
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:05:03
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	17 Nov 2020 17:04:35
User entered 'Jan 2010'	System	06 Sep 2020 18:42:25
User entered 'Aug 2020'	System	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2015'	System	17 Nov 2020 17:04:35
User entered '2010'	System	06 Sep 2020 18:42:25
User entered '2020'	System	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:29:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Aug 2020 20:29:12
Data point term sent to Coder	System	01 Aug 2020 20:28:21
User entered 'Postmenopausal'	Kayla Flege (b) (4)	01 Aug 2020 20:28:19
	(b) (4)	

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Start date of MH = UN UNK 2020. However, Post-menopausal date recorded in Childbearing eCRF is UN UNK 2002. Review if this should be reconciled. Else, Please clarify dates.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:10:23
Query 'Per DM CLR: Please note, Start date of MH = UN UNK 2020. However, Post-menopausal date recorded in Childbearing eCRF is UN UNK 2002. Review if this should be reconciled. Else, Please clarify dates.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:29:30
User entered 'UN UNK 2002' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:29:26
User opened query 'Per DM CLR: Please note, Start date of MH = UN UNK 2020. However, Post-menopausal date recorded in Childbearing eCRF is UN UNK 2002. Review if this should be reconciled. Else, Please clarify dates.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:59:20
User entered 'un UNK 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	01 Oct 2020 21:29:26
User entered 'Jan 2020'	System	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2002'	System	01 Oct 2020 21:29:26
User entered '2020'	System	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLG: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast imaging procedures, PT: Mammogram, LLT: Mammogram - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:19:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:19:46
Data point term sent to Coder	System	13 Nov 2020 18:18:59
User entered 'Mammogram'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '28 Jul 2020'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 18:18:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 18:18:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 18:18:55
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 18:18:48
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '28 Jul 2020'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:51
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:21:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:14:28
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:14:28
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'vitals in visit 1 day 1 as screening was done same day' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:43:11
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:55:33
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered 'Yes (Y)'	Kayla Flege (b) (4)	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:53
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:02
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:15:10
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '01 Aug 2020'	Kayla Flege (b) (4)	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:55
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:06
User entered '12:46' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:15:24
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '12:46'	Kayla Flege (b) (4)	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:46'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered '01 Aug 2020 12:46'	System	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Height (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:56
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:10
User entered '175.0' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:15:41
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '175.0' cm	Kayla Flege (b) (4)	01 Aug 2020 20:29:34
DataPoint set to visible.	(b) (4) System	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Weight (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:58
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:13
User entered '123.0' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:15:53
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '123.0' kg	Kayla Flege (b) (4)	01 Aug 2020 20:29:34
DataPoint set to visible.	(b) (4) System	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '40.16327'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered '40.2'	System	01 Aug 2020 20:29:34
DataPoint set to visible.	System	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'kg/m2'	System	01 Aug 2020 20:29:34
DataPoint set to visible.	System	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:48:01
Query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:16:17
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:16:17
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 23:27:36
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:28:22
	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '36.5' C	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered 'Other (Other)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered 'Tympanic'	Kayla Flege (b) (4)	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '80'	Kayla Flege (b) (4)	01 Aug 2020 20:29:34
	(b) (4)	

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'bpm'	System	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '20'	Kayla Flege (b) (4)	01 Aug 2020 20:29:34
	(b) (4)	

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'breaths/min'	System	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '125'	Kayla Flege (b) (4)	01 Aug 2020 20:29:34
	(b) (4)	

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'mmHg'	System	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '73'	Kayla Flege (b) (4)	01 Aug 2020 20:29:34
	(b) (4)	

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'mmHg'	System	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:46

US3272031

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:04:15
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		02 Sep 2020 20:21:08
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:36
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:46

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:18

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 20:31:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 20:31:19
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Aug 2020 20:31:19
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 20:30:40
User entered empty.	Kayla Flege (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Other

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'Biking, grocery shopping, socialization with friends.'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'I'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:18

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:16
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:32

US3272031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:16
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:32

US3272031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:16
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:32

US3272031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Aug 2020 20:31:32

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:44:09

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

What was the participant's randomization number?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:38:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:38:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 18:44:09
User entered '184340' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:44:09

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:44:09

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

US3272031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:18

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:18

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:23:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:02:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:36
User entered '175.0' cm	Kayla Flege (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:18

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:50:08
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:47
User entered '123.0' kg	Kayla Flege (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:18

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:23:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:02:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:36
User entered '175.0' cm	Kayla Flege (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:18

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:50:08
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:47
User entered '123.0' kg	Kayla Flege (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '12:46'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:46'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:01:28
User entered 'Tympanic'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Pulse (xxx)

Audit	User	Time (GMT)
User entered '80'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '20'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '125'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '73'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:18

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:23:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:02:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:36
User entered '175.0' cm	Kayla Flege (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:18

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:50:08
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:47
User entered '123.0' kg	Kayla Flege (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:18:22
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes per protocol' (Site from System).	Kayla Flege (b) (4)	01 Aug 2020 20:34:02
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	01 Aug 2020 20:33:38
User entered '14:39'	Kayla Flege (b) (4)	01 Aug 2020 20:33:38
	(b) (4)	

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 14:39'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:01:28
User entered 'Tympanic'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Pulse (xxx)

Audit	User	Time (GMT)
User entered '78'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '18'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:48
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:36:28

US3272031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:48
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:36:28

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	01 Aug 2020 20:36:47
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	01 Aug 2020 20:36:47
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	01 Aug 2020 19:16:06
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered '14:09'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 14:09'	System	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Aug 2020 20:36:47
User entered empty.	(b) (4)	
	Kayla Flege (b) (4)	01 Aug 2020 19:16:06
	(b) (4)	

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered 'ONCE'	System	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 19:16:06

US3272031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:53
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:04

US3272031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:53
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:04

US3272031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:53
User entered '13:26'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:04

US3272031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:26'	System	01 Aug 2020 20:37:04

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:18

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:11'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:11'	System	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:18

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 20:37:21

US3272031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:58
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:38:34

US3272031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:38:34

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:51:45', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '77c4796c-dd42-49d7-8cf0-47c66b7eb7ee'	System	01 Aug 2020 19:52:24
User entered 'Yes (Y)'	System	01 Aug 2020 19:52:24

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:51:55', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '77c4796c-dd42-49d7-8cf0-47c66b7eb7ee'	System	01 Aug 2020 19:52:24
User entered '97.8'	System	01 Aug 2020 19:52:24

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:52:03', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '77c4796c-dd42-49d7-8cf0-47c66b7eb7ee'	System	01 Aug 2020 19:52:24
User entered 'No (N)'	System	01 Aug 2020 19:52:24

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:52:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '77c4796c-dd42-49d7-8cf0-47c66b7eb7ee'	System	01 Aug 2020 19:52:24
User entered '01 Aug 2020 14:52'	System	01 Aug 2020 19:52:24

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 14:29'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 16:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T17:59:23', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '565e3e07-20a7-4c96-911a-803be959e428'	System	01 Aug 2020 23:02:04
User entered 'Yes (Y)'	System	01 Aug 2020 23:02:04

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:01:25', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '565e3e07-20a7-4c96-911a-803be959e428'	System	01 Aug 2020 23:02:04
User entered '97.4'	System	01 Aug 2020 23:02:04

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:01:39', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '565e3e07-20a7-4c96-911a-803be959e428'	System	01 Aug 2020 23:02:04
User entered 'No (N)'	System	01 Aug 2020 23:02:04

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '565e3e07-20a7-4c96-911a-803be959e428'	System	01 Aug 2020 23:02:04
User entered '01 Aug 2020 18:02'	System	01 Aug 2020 23:02:04

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 17:54'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 2'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:04:30', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6f833856-054e-4107-9957-fb21220ce6bf'	System	02 Aug 2020 21:04:59
User entered 'Yes (Y)'	System	02 Aug 2020 21:04:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:04:38', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6f833856-054e-4107-9957-fb21220ce6bf'	System	02 Aug 2020 21:04:59
User entered '96.0'	System	02 Aug 2020 21:04:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:04:43', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6f833856-054e-4107-9957-fb21220ce6bf'	System	02 Aug 2020 21:04:59
User entered 'No (N)'	System	02 Aug 2020 21:04:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:04:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6f833856-054e-4107-9957-fb21220ce6bf'	System	02 Aug 2020 21:04:59
User entered '02 Aug 2020 16:04'	System	02 Aug 2020 21:04:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 3'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:55:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:01:27', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '482aeac0-39e6-4f0a-9b98-8025f15c501d'	System	03 Aug 2020 20:01:57
User entered 'Yes (Y)'	System	03 Aug 2020 20:01:57

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:55:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:01:35', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '482aeac0-39e6-4f0a-9b98-8025f15c501d'	System	03 Aug 2020 20:01:57
User entered '98.6'	System	03 Aug 2020 20:01:57

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:01:41', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '482aeac0-39e6-4f0a-9b98-8025f15c501d'	System	03 Aug 2020 20:01:57
User entered 'No (N)'	System	03 Aug 2020 20:01:57

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:01:54', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '482aeac0-39e6-4f0a-9b98-8025f15c501d'	System	03 Aug 2020 20:01:57
User entered '03 Aug 2020 15:01'	System	03 Aug 2020 20:01:57

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 4'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:29:39', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '62a5734f-3211-4a7d-ba1b-b230b1b36e2b'	System	04 Aug 2020 20:30:05
User entered 'Yes (Y)'	System	04 Aug 2020 20:30:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:29:48', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '62a5734f-3211-4a7d-ba1b-b230b1b36e2b'	System	04 Aug 2020 20:30:05
User entered '97.9'	System	04 Aug 2020 20:30:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:29:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '62a5734f-3211-4a7d-ba1b-b230b1b36e2b'	System	04 Aug 2020 20:30:05
User entered 'No (N)'	System	04 Aug 2020 20:30:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '62a5734f-3211-4a7d-ba1b-b230b1b36e2b'	System	04 Aug 2020 20:30:05
User entered '04 Aug 2020 15:30'	System	04 Aug 2020 20:30:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 5'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:55:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:46:36', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'bcfa2ecb-4d90-4ae7-a7e6-e2cb14552dbf'	System	05 Aug 2020 19:47:05
User entered 'Yes (Y)'	System	05 Aug 2020 19:47:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:55:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:46:45', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'bcfa2ecb-4d90-4ae7-a7e6-e2cb14552dbf'	System	05 Aug 2020 19:47:05
User entered '96.9'	System	05 Aug 2020 19:47:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:46:51', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'bcfa2ecb-4d90-4ae7-a7e6-e2cb14552dbf'	System	05 Aug 2020 19:47:05
User entered 'No (N)'	System	05 Aug 2020 19:47:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:46:59', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'bcfa2ecb-4d90-4ae7-a7e6-e2cb14552dbf'	System	05 Aug 2020 19:47:05
User entered '05 Aug 2020 14:46'	System	05 Aug 2020 19:47:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 6'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:55:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:52:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '940b54f0-20e2-4ca3-893a-bb73f44f320f'	System	06 Aug 2020 18:53:13
User entered 'Yes (Y)'	System	06 Aug 2020 18:53:13

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:55:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:52:54', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '940b54f0-20e2-4ca3-893a-bb73f44f320f'	System	06 Aug 2020 18:53:13
User entered '96.3'	System	06 Aug 2020 18:53:13

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '940b54f0-20e2-4ca3-893a-bb73f44f320f'	System	06 Aug 2020 18:53:13
User entered 'No (N)'	System	06 Aug 2020 18:53:13

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:07', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '940b54f0-20e2-4ca3-893a-bb73f44f320f' User entered '06 Aug 2020 13:53'	System	06 Aug 2020 18:53:13
	System	06 Aug 2020 18:53:13

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 7'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:55:18

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:16:39', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'ac3583a5-f008-479e-b6c3-8eeb1230c166'	System	07 Aug 2020 19:17:16
User entered 'Yes (Y)'	System	07 Aug 2020 19:17:16

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:55:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:16:54', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'ac3583a5-f008-479e-b6c3-8eeb1230c166'	System	07 Aug 2020 19:17:16
User entered '97.9'	System	07 Aug 2020 19:17:16

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'ac3583a5-f008-479e-b6c3-8eeb1230c166'	System	07 Aug 2020 19:17:16
User entered 'No (N)'	System	07 Aug 2020 19:17:16

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'ac3583a5-f008-479e-b6c3-8eeb1230c166'	System	07 Aug 2020 19:17:16
User entered '07 Aug 2020 14:17'	System	07 Aug 2020 19:17:16

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:52:53', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered 'None (1)'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered 'No (N)'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:09', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered 'No (N)'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered 'None (1)'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:28', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered '01 Aug 2020 14:53'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 14:29'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 16:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered 'None (1)'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered 'No (N)'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:21', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered 'No (N)'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:38', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered 'None (1)'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:44', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered '01 Aug 2020 18:02'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 17:54'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 2'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered 'None (1)'	System	02 Aug 2020 21:05:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered 'No (N)'	System	02 Aug 2020 21:05:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered 'No (N)'	System	02 Aug 2020 21:05:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:24', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered 'None (1)'	System	02 Aug 2020 21:05:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:37', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered '02 Aug 2020 16:05'	System	02 Aug 2020 21:05:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 3'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:02', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered 'None (1)'	System	03 Aug 2020 20:02:36

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered 'No (N)'	System	03 Aug 2020 20:02:36

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:14', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered 'No (N)'	System	03 Aug 2020 20:02:36

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:25', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered 'None (1)'	System	03 Aug 2020 20:02:36

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:31', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered '03 Aug 2020 15:02'	System	03 Aug 2020 20:02:36

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 4'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:08', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered 'None (1)'	System	04 Aug 2020 20:30:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered 'No (N)'	System	04 Aug 2020 20:30:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:17', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered 'No (N)'	System	04 Aug 2020 20:30:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:22', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered 'None (1)'	System	04 Aug 2020 20:30:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:28', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered '04 Aug 2020 15:30'	System	04 Aug 2020 20:30:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 5'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:09', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered 'None (1)'	System	05 Aug 2020 19:47:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:13', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered 'No (N)'	System	05 Aug 2020 19:47:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:17', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered 'No (N)'	System	05 Aug 2020 19:47:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:22', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered 'None (1)'	System	05 Aug 2020 19:47:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:30', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered '05 Aug 2020 14:47'	System	05 Aug 2020 19:47:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 6'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:14', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered 'None (1)'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:18', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered 'No (N)'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:22', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered 'No (N)'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:27', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered 'None (1)'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:31', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered '06 Aug 2020 13:53'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 7'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered 'None (1)'	System	07 Aug 2020 19:18:03

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:24', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered 'No (N)'	System	07 Aug 2020 19:18:03

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:32', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered 'No (N)'	System	07 Aug 2020 19:18:03

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:41', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered 'None (1)'	System	07 Aug 2020 19:18:03

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered '07 Aug 2020 14:17'	System	07 Aug 2020 19:18:03

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:35', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:40', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:51', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:54', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:57', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:54:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'No (N)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:54:20', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered '01 Aug 2020 14:54'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 14:29'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 16:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:49', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:53', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:07', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:13', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'No (N)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:30', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered '01 Aug 2020 18:03'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 17:54'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 2'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:44', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:49', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:59', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:06:02', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:06:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'No (N)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:06:20', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered '02 Aug 2020 16:06'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 3'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:40', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:43', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:50', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:53', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:03:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'No (N)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:03:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered '03 Aug 2020 15:03'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 4'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:35', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:38', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:42', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:46', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:49', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:31:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'No (N)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:31:07', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered '04 Aug 2020 15:31'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 5'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:37', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:40', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:43', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:46', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:50', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:58', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'No (N)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:48:04', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered '05 Aug 2020 14:48'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 6'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:38', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:41', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:43', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:46', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:55', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:54:03', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'No (N)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:54:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered '06 Aug 2020 13:54'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 7'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:53', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:58', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:02', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:05', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:15', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'No (N)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:25', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered '07 Aug 2020 14:18'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:54
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:31

US3272031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:54
User entered '10 Aug 2020'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:31

US3272031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:54
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:31

US3272031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:54
User entered empty.	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:31

US3272031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:12:10
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:49

US3272031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 00:22:49

US3272031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:19:13

US3272031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '17 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 20:19:13

US3272031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 20:19:13

US3272031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:19:13

US3272031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:19:16

US3272031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 20:19:16

US3272031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:19:25

US3272031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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), (b) (6)	10 Sep 2020 12:26:12
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.'	(b) (4), (b) (6)	02 Sep 2020 20:19:32
answered with 'confirm correct' (Site from System).		
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).	System	02 Sep 2020 20:19:25
User entered '26 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 20:19:25

US3272031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 20:19:25

US3272031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:19:25

US3272031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:20:37

US3272031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 20:20:37

US3272031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:21:08

US3272031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:21:08

US3272031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Sep 2020 20:21:08

US3272031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	02 Sep 2020 20:21:08

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '12:10'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:10'	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.3' C	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:22:56

US3272031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:22:56

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Physician Decision (PHYSICIAN DECISION)'	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Patient has breast cancer and will be undergoing radiation'	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:24:21

US3272031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:24:21

US3272031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:35'	(b) (4), (b) (6)	02 Sep 2020 20:24:21

US3272031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:35'	System	02 Sep 2020 20:24:21

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:18

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:29'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:29'	System	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:18

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:24:43

US3272031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:24:43

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:22:23

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:22:23

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 23:22:23

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:22:23

US3272031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:22:16

US3272031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 23:22:16

US3272031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:27

US3272031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:33:27

US3272031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 15:33:27

US3272031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:33:27

US3272031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:30

US3272031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 15:33:30

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:37

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:33:37

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 15:33:37

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:33:37

US3272031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:40

US3272031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 15:33:40

US3272031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:58:34

US3272031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:58:34

US3272031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:58:34

US3272031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	29 Sep 2020 17:58:34

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '11:56'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:56'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '16'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:11

US3272031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:11

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:23

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:23

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:06'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:23

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:06'	System	29 Sep 2020 17:59:23

US3272031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:29

US3272031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 17:59:29

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 64'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[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 (5ce5dc21d52e5733)', Time: '2020-10-05T09:21:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '3378afcc-c432-4070-856b-8fc87dc4de62'	System	05 Oct 2020 14:21:30
User entered 'No (N)'	System	05 Oct 2020 14:21:30

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Have you been exposed to someone with 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 (5ce5dc21d52e5733)', Time: '2020-10-05T09:21:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '3378afcc-c432-4070-856b-8fc87dc4de62'	System	05 Oct 2020 14:21:30
User entered 'No (N)'	System	05 Oct 2020 14:21:30

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-05T09:21:28', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '3378afcc-c432-4070-856b-8fc87dc4de62'	System	05 Oct 2020 14:21:30
User entered '05 Oct 2020 09:21:28'	System	05 Oct 2020 14:21:30

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '01 Oct 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '05 Oct 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 71'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[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 (5ce5dc21d52e5733)', Time: '2020-10-12T10:44:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '570c1918-ccd5-49b8-a40e-8eaf193e7a40'	System	12 Oct 2020 15:44:25
User entered 'No (N)'	System	12 Oct 2020 15:44:25

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Have you been exposed to someone with 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 (5ce5dc21d52e5733)', Time: '2020-10-12T10:44:08', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '570c1918-ccd5-49b8-a40e-8eaf193e7a40'	System	12 Oct 2020 15:44:25
User entered 'No (N)'	System	12 Oct 2020 15:44:25

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-12T10:44:23', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '570c1918-ccd5-49b8-a40e-8eaf193e7a40'	System	12 Oct 2020 15:44:25
User entered '12 Oct 2020 10:44:23'	System	12 Oct 2020 15:44:25

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '08 Oct 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '12 Oct 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 78'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[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 (5ce5dc21d52e5733)', Time: '2020-10-15T07:33:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '2e846fcf-b4be-4ff5-abc2-1fc8576a82d3'	System	15 Oct 2020 12:33:20
User entered 'No (N)'	System	15 Oct 2020 12:33:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Have you been exposed to someone with 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 (5ce5dc21d52e5733)', Time: '2020-10-15T07:33:15', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '2e846fcf-b4be-4ff5-abc2-1fc8576a82d3'	System	15 Oct 2020 12:33:20
User entered 'No (N)'	System	15 Oct 2020 12:33:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-15T07:33:20', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '2e846fcf-b4be-4ff5-abc2-1fc8576a82d3'	System	15 Oct 2020 12:33:20
User entered '15 Oct 2020 07:33:20'	System	15 Oct 2020 12:33:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '15 Oct 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '19 Oct 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 92'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[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 (5ce5dc21d52e5733)', Time: '2020-10-29T07:13:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '58cd2b3a-be6a-415d-822e-91e191e13cb6'	System	29 Oct 2020 12:14:20
User entered 'No (N)'	System	29 Oct 2020 12:14:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Have you been exposed to someone with 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 (5ce5dc21d52e5733)', Time: '2020-10-29T07:13:57', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '58cd2b3a-be6a-415d-822e-91e191e13cb6'	System	29 Oct 2020 12:14:20
User entered 'No (N)'	System	29 Oct 2020 12:14:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-29T07:14:17', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '58cd2b3a-be6a-415d-822e-91e191e13cb6'	System	29 Oct 2020 12:14:20
User entered '29 Oct 2020 07:14:17'	System	29 Oct 2020 12:14:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '29 Oct 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '02 Nov 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 99'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[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 (5ce5dc21d52e5733)', Time: '2020-11-05T10:16:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6b537f5a-e5d0-4779-9247-04ea56b716d1'	System	05 Nov 2020 16:16:19
User entered 'No (N)'	System	05 Nov 2020 16:16:19

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Have you been exposed to someone with 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 (5ce5dc21d52e5733)', Time: '2020-11-05T10:16:13', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6b537f5a-e5d0-4779-9247-04ea56b716d1'	System	05 Nov 2020 16:16:19
User entered 'No (N)'	System	05 Nov 2020 16:16:19

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-05T10:16:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6b537f5a-e5d0-4779-9247-04ea56b716d1'	System	05 Nov 2020 16:16:19
User entered '05 Nov 2020 10:16:16'	System	05 Nov 2020 16:16:19

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '05 Nov 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '09 Nov 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 106'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[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 (5ce5dc21d52e5733)', Time: '2020-11-12T07:37:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b8e42ce8-be6e-4825-a294-89df8b794a75'	System	12 Nov 2020 13:37:23
User entered 'No (N)'	System	12 Nov 2020 13:37:23

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Have you been exposed to someone with 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 (5ce5dc21d52e5733)', Time: '2020-11-12T07:37:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b8e42ce8-be6e-4825-a294-89df8b794a75'	System	12 Nov 2020 13:37:23
User entered 'No (N)'	System	12 Nov 2020 13:37:23

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-12T07:37:22', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b8e42ce8-be6e-4825-a294-89df8b794a75'	System	12 Nov 2020 13:37:23
User entered '12 Nov 2020 07:37:22'	System	12 Nov 2020 13:37:23

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '12 Nov 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '16 Nov 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '28 Sep 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '02 Oct 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '05 Oct 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '09 Oct 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '12 Oct 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '16 Oct 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '19 Oct 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '23 Oct 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[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 (5ce5dc21d52e5733)', Time: '2020-11-19T07:16:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7abbd46a-d3de-4786-840c-1ee628cf91f4'	System	19 Nov 2020 13:17:11
User entered 'No (N)'	System	19 Nov 2020 13:17:11

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Have you been exposed to someone with 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 (5ce5dc21d52e5733)', Time: '2020-11-19T07:17:05', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7abbd46a-d3de-4786-840c-1ee628cf91f4'	System	19 Nov 2020 13:17:11
User entered 'No (N)'	System	19 Nov 2020 13:17:11

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-19T07:17:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7abbd46a-d3de-4786-840c-1ee628cf91f4'	System	19 Nov 2020 13:17:11
User entered '19 Nov 2020 07:17:10'	System	19 Nov 2020 13:17:11

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[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 (5ce5dc21d52e5733)', Time: '2020-11-23T07:38:42', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a2940f0-d654-43f5-b67e-d437f78d7c10'	System	23 Nov 2020 13:39:00
User entered 'No (N)'	System	23 Nov 2020 13:39:00

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

Have you been exposed to someone with 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 (5ce5dc21d52e5733)', Time: '2020-11-23T07:38:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a2940f0-d654-43f5-b67e-d437f78d7c10'	System	23 Nov 2020 13:39:00
User entered 'No (N)'	System	23 Nov 2020 13:39:00

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-23T07:38:59', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a2940f0-d654-43f5-b67e-d437f78d7c10'	System	23 Nov 2020 13:39:00
User entered '23 Nov 2020 07:38:59'	System	23 Nov 2020 13:39:00

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 14:58:33

US3272031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 14:58:33

US3272031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Oct 2020 14:58:33

US3272031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 14:58:33

US3272031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 14:58:39

US3272031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Oct 2020 14:58:39

US3272031

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:55:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:18:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Aug 2020 21:45:23
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	10 Aug 2020 17:11:11

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:15:43
User entered	System	19 Aug 2020 17:15:36
'USA-US070-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	19 Aug 2020 17:15:36

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'Per DM CLR: Please specify the location of STAGE 1 BREAST CANCER (e.g. Left, Right or Bilateral). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:51:42
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer stage I, LLT: Breast cancer stage I - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:39:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:39:24
Query 'Per DM CLR: Please specify the location of STAGE 1 BREAST CANCER (e.g. Left, Right or Bilateral). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:40:48
Data point term sent to Coder	System	30 Sep 2020 18:40:46
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:40:44
User entered 'STAGE 1 LEFT BREAST CANCER' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:40:44
User opened query 'Per DM CLR: Please specify the location of STAGE 1 BREAST CANCER (e.g. Left, Right or Bilateral). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 06:03:22
User closed query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:16

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer stage I, LLT: Breast cancer stage I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:09:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:09:54
Data point term sent to Coder	System	14 Sep 2020 16:08:28
Query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' answered with 'Updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:08:04
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:07:28
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:07:28
User entered 'Stage 1 BREAST CANCER' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:07:28
User opened query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:58:54
User closed query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:05
Query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' answered with 'Unknown at this time. Waiting on medical records.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:38:28
User opened query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:41:58
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:33:46
Data point term sent to Coder	System	18 Aug 2020 21:48:22

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Breast Cancer'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 13:21:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 13:21:54
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	27 Aug 2020 13:21:54
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 13:29:27
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 13:29:27
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:38:42

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'PV Query: On 28 July 2020, a breast lump was detected during a routine mammogram. Please consider updating event start date to 28 JUL 2020. ' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 15:21:54
Query 'PV Query: On 28 July 2020, a breast lump was detected during a routine mammogram. Please consider updating event start date to 28 JUL 2020. ' answered with 'Diagnosis wasnt until 17 AUG 2020' (Site from Safety).	Kayla Flege (b) (4)	30 Sep 2020 18:41:50
User closed query 'Adverse Event Start Date is beforeSystem treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	30 Sep 2020 18:41:37
User closed query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		30 Sep 2020 18:41:37
User entered '17 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	30 Sep 2020 18:41:37
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	30 Sep 2020 18:41:04
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	30 Sep 2020 18:41:04
User entered '28 Jul 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	30 Sep 2020 18:41:04
User opened query 'PV Query: On 28 July 2020, a breast lump was detected during a routine mammogram. Please consider updating event start date to 28 JUL 2020. ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 11:21:30

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:32
	Kayla Flege (b) (4)	14 Sep 2020 16:14:59
User entered '14 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	14 Sep 2020 16:14:59
Query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' answered with 'Date is correct.' (Site from Safety).	Kayla Flege (b) (4)	14 Sep 2020 16:08:43
User opened query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 15:59:40
	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '17 Aug 2020'	Kayla Flege (b) (4)	18 Aug 2020 21:47:43
	(b) (4)	

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
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).	System	18 Aug 2020 21:48:37
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:48:37
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Aug 2020 21:47:43
User entered '10:30'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 21:48:37
User entered '17 Aug 2020 10:30'	System	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Un-verified.	Kayla Flege (b) (4)	27 Aug 2020 13:21:54
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	27 Aug 2020 13:21:54
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Yes (Y)'	Kayla Flege (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:54:23
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 16:21:18
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Kayla Flege (b) (4)	27 Aug 2020 13:22:45
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Completed' (Site from Safety).	Kayla Flege (b) (4)	27 Aug 2020 13:22:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	27 Aug 2020 13:21:54
DataPoint Un-verified.	Kayla Flege (b) (4)	27 Aug 2020 13:21:54
User entered '27 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	27 Aug 2020 13:21:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:27:57
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'I'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'None (NONE)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'I'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 16:21:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Recovered.' (Site from Safety).	Kayla Flege (b) (4)	27 Aug 2020 13:24:48
DataPoint Un-verified.	Kayla Flege (b) (4)	27 Aug 2020 13:24:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Kayla Flege (b) (4)	27 Aug 2020 13:24:37
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kayla Flege (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted ' 'Subject had mammogram before study started' however, this surgery/procedure is not recorded on the Med Hist eCRF? Please review and update MH as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:43:24
Query 'Per CDM: Response noted ' 'Subject had mammogram before study started' however, this surgery/procedure is not recorded on the Med Hist eCRF? Please review and update MH as appropriate.'	(b) (4), (b) (6)	13 Nov 2020 18:17:13
answered with 'Med history updated to include mammogram. ' (Site from DM).		
User opened query 'Per CDM: Response noted ' 'Subject had mammogram before study started' however, this surgery/procedure is not recorded on the Med Hist eCRF? Please review and update MH as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:22:03
User closed query 'Per DM CLR: As per SAE narrative, "BIOPSY PERFORMED ON 05 AUG 2020", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:02:18
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:57:44
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Subject had mammogram before study started' (Site from DM).	Kayla Flege (b) (4) (b) (4)	02 Nov 2020 21:58:37
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:16:28

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 15:21:50
Query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 19:30:08
User entered 'SUBJECT DIAGNOSED WITH STAGE 1 BREAST CANCER. SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. BIOPSY PERFORMED ON 05 AUG 2020. SUBJECT SCHEDULED TO HAVE A LUMPECTOMY ON 26 AUG 2020. Pathology of both masses reveled invasive ductal carcinoma, grade 2, ER/PR 100% positive, her-2 negative, perineural invasion present and DCIS.' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 19:29:51
Query 'Per DM CLR: As per SAE narrative, "BIOPSY PERFORMED ON 05 AUG 2020", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:43:03
User opened query 'Per DM CLR: As per SAE narrative, "BIOPSY PERFORMED ON 05 AUG 2020", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 06:04:23
User closed query 'PV Query: How was breast cancer detected (i.e routine mammography, breast self-exam, etc)?' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:52

v6.020 DTW (1102)

1437 of 1778

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if patient will receive any additional treatment, besides lumpectomy (i.e. radiation, chemotherapy)? ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:49
User closed query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:46
User closed query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:44
Query 'PV Query: How was breast cancer detected (i.e routine mammography, breast self-exam, etc)?' answered with 'Routine Mammography.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:17:20
Query 'PV Query: Please confirm if patient will receive any additional treatment, besides lumpectomy (i.e. radiation, chemotherapy)? ' answered with 'Yes, she is receiving radiation at this time.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:16:50
Query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' answered with 'menorrhagia-noted in medical hx' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:16:14
Query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' answered with 'updated.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:15:31
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:14:59
User entered 'SUBJECT DIAGNOSED WITH Stage 1 BREAST CANCER. Subject had a routine mammogram completed on 28 JUL 2020. Biopsy preformed on 05 AUG 2020. SUBJECT SCHEDULED TO HAVE A LUMPECTOMY ON 26 AUG 2020.' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:14:59
User opened query 'PV Query: How was breast cancer detected (i.e routine mammography, breast self-exam, etc)?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:00:20
User opened query 'PV Query: Please confirm if patient will receive any additional treatment, besides lumpectomy (i.e. radiation, chemotherapy)? ' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:00:14

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:59:14
User opened query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:58:36
User opened query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:58:29
User closed query 'Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:19:09
User closed query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:19:04
User closed query 'PV Query: Did the subject have any risk factors for the breast cancer (i.e. nulliparity or low parity, genetic markers (BRCA1 or BRCA 2), family Hx of cancer, estrogen use, etc)?' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:46
User closed query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:43
User closed query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:32
User closed query 'PV Query: Please confirm if patient will see an oncologist for the event and if additional treatment will be required (chemo, radiation, etc).' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:29

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:25
User closed query 'PV Query: Please confirm that the lumpectomy was performed on 26 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:23
User closed query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:18
Query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' answered with 'ok' (Site from Safety).	Kayla Flege (b) (4)	06 Sep 2020 18:41:41
Query 'PV Query: Did the subject have any risk factors for the breast cancer (i.e. nulliparity or low parity, genetic markers (BRCA1 or BRCA 2), family Hx of cancer, estrogen use, etc)?' answered with 'No.' (Site from Safety).	Kayla Flege (b) (4)	06 Sep 2020 18:41:38
Query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' answered with 'Waiting on medical records.' (Site from Safety).	Kayla Flege (b) (4)	06 Sep 2020 18:41:26
Query 'PV Query: Please confirm if patient will see an oncologist for the event and if additional treatment will be required (chemo, radiation, etc).' answered with 'Yes.' (Site from Safety).	Kayla Flege (b) (4)	06 Sep 2020 18:41:05
Query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' answered with 'Will send once reports are back.' (Site from Safety).	Kayla Flege (b) (4)	06 Sep 2020 18:40:57
Query 'PV Query: Please confirm that the lumpectomy was performed on 26 Aug 2020.' answered with 'Yes it was.' (Site from Safety).	Kayla Flege (b) (4)	06 Sep 2020 18:39:31

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' answered with 'Waiting on medical records.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:39:18
User opened query 'PV Query: Did the subject have any risk factors for the breast cancer (i.e. nulliparity or low parity, genetic markers (BRCA1 or BRCA 2), family Hx of cancer, estrogen use, etc)?' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:42:42
User opened query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:42:31
User opened query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:42:23
User opened query 'PV Query: Please confirm if patient will see an oncologist for the event and if additional treatment will be required (chemo, radiation, etc).' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:42:14
User opened query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:41:41
User opened query 'PV Query: Please confirm that the lumpectomy was performed on 26 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:41:29
User opened query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:41:17
User closed query 'PV Query: Has the patient been seen by an oncologist? If so, please provide diagnosis and assessment by oncologist.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 16:22:39

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 16:22:21
User closed query 'PV Query: Please provide initial signs and symptoms. Did the patient discovery abnormality or was this found during routine screening?' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 16:22:10
Query 'PV Query: Has the patient been seen by an oncologist? If so, please provide diagnosis and assessment by oncologist.' answered with 'NA' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:24:28
Query 'PV Query: Please provide initial signs and symptoms. Did the patient discovery abnormality or was this found during routine screening?' answered with 'This was found during routine screening prior to randomization day' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:24:09
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'No medications taken' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:23:41
Query 'Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Lumpectomy 26 AUG 2020' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:23:26
Query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'In patient chart' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:23:11
User opened query 'PV Query: Has the patient been seen by an oncologist? If so, please provide diagnosis and assessment by oncologist.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:29:16

v6.020 DTW (1102)

1442 of 1778

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide initial signs and symptoms. Did the patient discovery abnormality or was this found during routine screening?' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:29:06
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:27:20
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User opened query 'Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	21 Aug 2020 02:17:33
User opened query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Aug 2020 02:17:15
User entered 'Subject diagnosed with breast cancer. Subject scheduled to have a lumpectomy on 26 AUG 2020.'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 01:38:45
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:38:42

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 01:38:45
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:38:42

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:38:42

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:55:18

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:29:57

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
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)	01 Oct 2020 21:33:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:33:01
Data point term sent to Coder	System	01 Oct 2020 21:31:44
User entered 'Levothyroxine'	Kayla Flege (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Graves Disease'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '175'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:33:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:33:48
Data point term sent to Coder	System	01 Oct 2020 21:32:49
User entered 'Losartan potassium/hydrochlorothiazide'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '125/100'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: METFORMIN ER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:34:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:34:50
Data point term sent to Coder	System	01 Oct 2020 21:33:53
User entered 'Metformin ER'	Kayla Flege (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Type 2 Diabetes'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:37:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:37:13
Data point term sent to Coder	System	01 Oct 2020 21:35:57
User entered 'Benadryl'	Kayla Flege (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Seasonal Allergies'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:37:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:37:52
Data point term sent to Coder	System	01 Oct 2020 21:37:00
User entered 'Multivitamin'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Nutritional Supplement'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013' reason for change:	(b) (4), (b) (6)	17 Nov 2020 17:13:32
Data Entry Error		
User entered 'un UNK 2000'	Kayla Flege (b) (4)	01 Oct 2020 21:36:49
	(b) (4)	

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: AMINO ACIDS AND DERIVATIVES, PRODUCT: LYSINE, PRODUCTSYNONYM: L-LYSINE [LYSINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 08:11:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 08:11:46
Data point term sent to Coder	System	01 Oct 2020 21:39:04
User entered 'L-lysine'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Herpes Simplex 1'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 1975'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
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)	01 Oct 2020 21:39:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:39:54
Data point term sent to Coder	System	01 Oct 2020 21:39:04
User entered 'Omeprazole'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gastroesophageal Reflux Disease'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:41:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:41:56
Data point term sent to Coder	System	01 Oct 2020 21:41:06
User entered 'Vitamin D3'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Nutritional Supplement'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 17:14:38
Data Entry Error		
User entered 'ug (ug)'	Kayla Flege (b) (4)	01 Oct 2020 21:40:23
	(b) (4)	

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:14:38
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '15 Jul 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Oct 2020 21:41:36
User entered '15 Jun 2020'	Kayla Flege (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:28:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:28:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:42:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:42:57
Data point term sent to Coder	System	01 Oct 2020 21:42:07
User entered 'Vitamin B'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Nutritional Supplement'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '15 Jul 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:43:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:43:59
Data point term sent to Coder	System	01 Oct 2020 21:43:08
User entered 'Symbicort'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Emphysema'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '15 May 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 04:49:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 04:49:40
Data point term sent to Coder	System	01 Oct 2020 21:44:11
User entered 'Clobetasol Propionate'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Lichen Scleroses'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'NA'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:43:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 21:43:54
User entered 'Other (OTHER)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:54
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:43:46
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	01 Oct 2020 21:43:59
User entered 'NA' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Oct 2020 21:43:59
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	01 Oct 2020 21:43:54
User entered empty.	Kayla Flege (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'twice a week'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CIMICIFUGA RACEMOSA, PRODUCTSYNONYM: BLACK COHOSH [CIMICIFUGA RACEMOSA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:46:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:46:02
Data point term sent to Coder	System	01 Oct 2020 21:45:14
User entered 'Black Cohosh'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Vasomotor Symptoms'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '540'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:46:49
Data point term sent to Coder	System	01 Oct 2020 21:46:14
User entered 'Flu Shot'	Kayla Flege (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Influenza Prophylaxis'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:55:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	27 Aug 2020 13:26:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 17:11:19

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:27:11

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Lumpectomy'	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:27:11

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:27:11

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:18

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:27:11

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:55:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Aug 2020'	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:42:52

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:55:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Biopsy on Left Breast'	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:42:52

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:55:18

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diagnostic (DIAGNOSTIC)'	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:42:52

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:55:18

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:42:52

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered '19/Aug/2020 13:16'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:55:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '27/Aug/2020 12:20'	System	27 Aug 2020 16:20:04

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:55:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'I'	(b) (4), (b) (6)	27 Aug 2020 16:20:04

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:55:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '09/Sep/2020 21:14'	System	10 Sep 2020 01:14:22

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:55:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 01:14:22

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:55:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '15/Sep/2020 09:30'	System	15 Sep 2020 13:30:13

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:55:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 13:30:13