

US3562205 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:13:36

All time stamps listed in this document are displayed in GMT

US3562205

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 22:22:02

Generated On: 10 Jun 2021 08:13:36

Participant ID

US3562205

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

US3562205

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Screening

Form: Demographics

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
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	False
Black	True
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

US3562205

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3562205

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Were any significant conditions reported?

Yes ☒

No ☐

US3562205

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	LEFT EAR INFECTION
Start date (dd MMM yyyy)	07 SEP 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)	15 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

US3562205

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	CHRONIC CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3562205

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	UTERINE ABLATION
Start date (dd MMM yyyy)	UN UNK 2001
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3562205

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	ACCESSIBLE VAGINAL BLEEDING
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3562205

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562205

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3562205

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	SLEEP APNEA
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)	

US3562205

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

US3562205

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Condition	DIVERTICULITIS
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3562205

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:54
Height (xxx.x)	66 in
Weight (xxx.x)	317 lb
BMI (xxx.x)	51.27212 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562205

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3562205

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Date of assessment (dd MMM yyyy) 1 OCT 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

US3562205

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	1 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3562205

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3562205

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

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	

US3562205

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 16:42:13

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 10 Mar 2021 16:42:13

Generated On: 10 Jun 2021 08:13:36

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

What was the participant's randomization number? 146851

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☒ No ☐

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 10 Mar 2021 16:42:13

Generated On: 10 Jun 2021 08:13:36

Height	ND - Not Done
Weight	ND - Not Done

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Mar 2021 16:42:13

Generated On: 10 Jun 2021 08:13:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:54
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Mar 2021 16:42:13

Generated On: 10 Jun 2021 08:13:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 12:08
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3562205

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 16:42:12

Generated On: 10 Jun 2021 08:13:36

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 10 Mar 2021 16:42:12

Generated On: 10 Jun 2021 08:13:36

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 10 Mar 2021 16:42:12

Generated On: 10 Jun 2021 08:13:36

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 OCT 2020

What was the treatment time? (00:00-23:59) 11:37 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 11:37

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

What was the frequency of the study treatment dosing? ONCE

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

US3562205

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 16:42:12

Generated On: 10 Jun 2021 08:13:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	11:15 (24 HR)
Collection date and time (derived)	1 OCT 2020 11:15

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Mar 2021 16:42:12

Generated On: 10 Jun 2021 08:13:36

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:20	1 OCT 2020 11:20
Nasopharyngeal Swab 2	No		

US3562205

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:42:12

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:13

PC Open Date & Time

01 OCT 2020 11:57

PC Close Date & Time

01 OCT 2020 14:27

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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 98.9 °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	01 OCT 2020 22:59
PC Open Date & Time	01 OCT 2020 15:22
PC Close Date & Time	02 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 18:52

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	03 OCT 2020 19:39
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

04 OCT 2020 18:29

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 18:04

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

06 OCT 2020 18:01

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

07 OCT 2020 18:57

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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 OCT 2020 12:14

PC Open Date & Time

01 OCT 2020 11:57

PC Close Date & Time

01 OCT 2020 14:27

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 23:00

PC Open Date & Time

01 OCT 2020 15:22

PC Close Date & Time

02 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 18:52

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 19:40

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

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 OCT 2020 18:29

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 18:04

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 18:01

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

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 OCT 2020 18:57

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 12:15
PC Open Date & Time	01 OCT 2020 11:57
PC Close Date & Time	01 OCT 2020 14:27

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 23:01
PC Open Date & Time	01 OCT 2020 15:22
PC Close Date & Time	02 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

56 of 2209

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 18:53
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 2209

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:40
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2209

EAB) (1725)

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 18:30
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2209

EAB) (1725)

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 18:05
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2209

EAB) (1725)

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 18:02
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

66 of 2209

EAB) (1725)

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 18:58
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3562205

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:42:10

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:42:10

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:42:08

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:42:08

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:42:08

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:42:08

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 22:02:41

Generated On: 10 Jun 2021 08:13:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 22:02:41

Generated On: 10 Jun 2021 08:13:36

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)	29 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 10:10
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 22:02:41

Generated On: 10 Jun 2021 08:13:36

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)	29 OCT 2020
Time of assessment (00:00-23:59)	11:26 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 11:26
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3562205

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:02:40

Generated On: 10 Jun 2021 08:13:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 22:02:40

Generated On: 10 Jun 2021 08:13:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	29 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 22:02:40

Generated On: 10 Jun 2021 08:13:36

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 OCT 2020

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 29 OCT 2020 10:55

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

What was the frequency of the study treatment dosing? ONCE

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

US3562205

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 22:02:40

Generated On: 10 Jun 2021 08:13:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 OCT 2020
Collection time (00:00-23:59)	10:17 (24 HR)
Collection date and time (derived)	29 OCT 2020 10:17

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 22:02:40

Generated On: 10 Jun 2021 08:13:36

Collection date (dd MMM yyyy)			29 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:40	29 OCT 2020 10:40
Nasopharyngeal Swab 2	No		

US3562205

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:02:40

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °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

29 OCT 2020 11:31

PC Open Date & Time

29 OCT 2020 11:15

PC Close Date & Time

29 OCT 2020 13:45

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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 99.4 °F

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

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

PC Time Stamp	29 OCT 2020 19:21
PC Open Date & Time	29 OCT 2020 14:40
PC Close Date & Time	30 OCT 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

100.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 OCT 2020 19:11

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False
PC Time Stamp	31 OCT 2020 19:11
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °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

01 NOV 2020 18:06

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 17:52

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 NOV 2020 21:53

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 NOV 2020 22:17

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

29 OCT 2020 11:31

PC Open Date & Time

29 OCT 2020 11:15

PC Close Date & Time

29 OCT 2020 13:45

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 19:22

PC Open Date & Time

29 OCT 2020 14:40

PC Close Date & Time

30 OCT 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 19:12

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

31 OCT 2020 19:11

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

01 NOV 2020 18:07

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

02 NOV 2020 17:53

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

03 NOV 2020 21:53

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

04 NOV 2020 22:17

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

No ☒

Yes ☐

PC Time stamp	29 OCT 2020 11:32
PC Open Date & Time	29 OCT 2020 11:15
PC Close Date & Time	29 OCT 2020 13:45

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

No ☒

Yes ☐

PC Time stamp	29 OCT 2020 19:22
PC Open Date & Time	29 OCT 2020 14:40
PC Close Date & Time	30 OCT 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

103 of 2209

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 19:12
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 2209

EAB) (1725)

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 19:11
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 2209

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 18:07
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

109 of 2209

EAB) (1725)

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 17:53
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

111 of 2209

EAB) (1725)

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 21:54
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

113 of 2209

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 22:18
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3562205

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:42:09

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:42:09

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:42:10

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:42:09

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:42:10

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:42:10

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 22:02:41

Generated On: 10 Jun 2021 08:13:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 NOV 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

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 22:02:41

Generated On: 10 Jun 2021 08:13:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	09:31 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 09:31
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562205

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:02:41

Generated On: 10 Jun 2021 08:13:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

US3562205

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 22:02:41

Generated On: 10 Jun 2021 08:13:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 NOV 2020
Collection time (00:00-23:59)	09:40 (24 HR)
Collection date and time (derived)	25 NOV 2020 09:40

US3562205

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:02:41

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 17:50:14
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 12:29:05
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 12:31:03
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 08:31:27
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 00:02:03
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 11:42:45
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 10:00:11

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 09:49:34
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 JAN 2021 19:58:48
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 12:31:02
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 07:48:20

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 09:11:55

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 12:43:48

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 12:37:13

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 11:01:32

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 12:40:10

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 MAR 2021 12:32:40
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 09:33:58
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 11:00:49

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 00:59:46

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 12:31:58

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 08:29:44

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 08:32:00

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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="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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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09 FEB 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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16 FEB 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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23 FEB 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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26 FEB 2022 00:01

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02 MAR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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09 MAR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐ Yes ☐

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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16 MAR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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19 MAR 2022 00:01

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23 MAR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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26 MAR 2022 00:01

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30 MAR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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06 APR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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13 APR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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27 APR 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

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04 MAY 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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13 JUL 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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="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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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17 AUG 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3562205

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:13:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 12:37:29

US3562205

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:42:11

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:42:11

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 17:35:00

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 17:35:01

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:10:07

Generated On: 10 Jun 2021 08:13:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562205

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:10:07

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 20:01:24

Generated On: 10 Jun 2021 08:13:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 20:01:24

Generated On: 10 Jun 2021 08:13:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 APR 2021
Time of assessment (00:00-23:59)	09:24 (24 HR)
Vital Signs Date and Time (derived)	16 APR 2021 09:24
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562205

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 20:01:24

Generated On: 10 Jun 2021 08:13:36

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3562205

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 20:01:24

Generated On: 10 Jun 2021 08:13:36

Was the sample collected? Yes ☒ No ☐

Collection date (dd MMM yyyy) 16 APR 2021

Collection time (00:00-23:59) 09:31 (24 HR)

Collection date and time (derived) 16 APR 2021 09:31

US3562205

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 20:01:24

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562205

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3562205

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:13:36

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"/>

US3562205

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:13:36

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3562205

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

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 18:46:09

Generated On: 10 Jun 2021 08:13:36

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

Visit date (dd MMM yyyy)	25 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3562205

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 18:46:09

Generated On: 10 Jun 2021 08:13:36

Date of updated informed consent (dd MMM yyyy) 25 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3562205

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 18:46:08

Generated On: 10 Jun 2021 08:13:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00-23:59)	08:32 (24 HR)
Collection date and time (derived)	25 JAN 2021 08:32

US3562205

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Mar 2021 18:46:08

Generated On: 10 Jun 2021 08:13:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	08:35
Collection Date and Time (derived)	25 JAN 2021 08:35

US3562205

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 22:09:01

Generated On: 10 Jun 2021 08:13:36

AEID	USA-US071-2021-MRNA-1273-P30 1000004
Adverse event	WORSENING OF DIVERTICULITIS
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)	20 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	24 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	338 of 2209

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 22:09:01

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 22:09:01

Generated On: 10 Jun 2021 08:13:36

DIVERTICULITIS DX OF 2013,
NO EPISODE UNTILL JAN20TH
21 , WENT TO ER-XRAY DONE
AND GOT ADMITTED TO
HOSPITAL, DISCHARGE ON
24TH JAN 21, UPDATED
CONMED XRAY ABDOMINAL
FINDING THERE IS NON
OBSRTUCTIVE BOWEL GAS
PATTERN. THERE IS NO
ABNORMAL DILATION OF
BOWEL LOOPS. THERE IS NO
PNEUMATOSIS OR MASS
EFFECT . COMPLETED COVID 19
PUI,FLU A/B, RSV RAPID PANEL
DONE ON 1/22/21 AND RESULTS
ARE NEGATIVE FOR COVID 19,
INFLUENZA A,B AND RSV, CT
WAS DONE ON 1/21/21 SHOWED
ACUTE SIGNMOID
DIVERTICULITIS WITH
MICROPERFORATION

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 22:09:01

Generated On: 10 Jun 2021 08:13:36

AEID	
Adverse event	WORSENING DIVERTICULITIS
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)	19 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 2209

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 22:09:01

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

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

Yes ☒

No ☐

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

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE CAFFEINE
WITHDRAWAL

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL CRAMP PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication LIOTHYRONINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication LEVOXYL

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication LOW GRADE
FEVER/FATIGUE/INJECTION
ARM PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
DIVERTICULITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING DIVERTICULITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication LEFT EAR INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication ALPRAZOLEM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication LINZESS

Prophylaxis Yes ☐
No ☒

Indication CHRONIC CONSTIPATION

Dose per administration 145

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL CRAMP PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication VITAMIN D2

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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 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 checked="" type="radio"/>
	804	<input type="radio"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

376 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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 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"/>

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING DIVERTICULITIS

Dose per administration 875

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 2209

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

	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)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 JAN 2021	CT SCAN	Adverse Event	
22 JAN 2021	ABDOMINAL X RAY VIEW	Adverse Event	

US3562205

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:13:36

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

US3562205

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:13:36

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 ☐

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

SAEID	USA-US071-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

SAEID	USA-US071-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/JAN/2021 12:56
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

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

SAEID	USA-US071-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/FEB/2021 13:23
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

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

SAEID	USA-US071-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/FEB/2021 12:08
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

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 22:09:02

Generated On: 10 Jun 2021 08:13:36

SAEID	USA-US071-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/FEB/2021 13:12
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

US3562205 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3562205

Form: Participant Creation

Generated On: 10 Jun 2021 08:13:36

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:22:02
User entered 'US3562205'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 17:53:03

US3562205

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:56:09

US3562205

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 17:53:04

US3562205

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:56:09

US3562205

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'SCRN'	System	03 Oct 2020 15:56:09

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered (b) (6) 1967'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 17:53:05

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '53'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'YEARS'	System	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '53'	System	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'l'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:41:38

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Oct 2020'	System	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2020'	System	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 18:41:56

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 17:53:04

US3562205

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'I'	System	01 Oct 2020 18:42:03

US3562205

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:42:03

US3562205

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:13:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:56:26

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Ear infection, LLT: Ear infection - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:41:45
Data point term sent to Coder	System	09 Oct 2020 23:40:22
User entered 'left ear infection'	Dhwani Shah (b) (4)	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '07 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '15 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Sep 2020'	System	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2020'	System	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Sep 2020'	System	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2020'	System	09 Oct 2020 23:39:51

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:41:45
Data point term sent to Coder	System	09 Oct 2020 23:40:22
User entered 'anxiety'	Dhwani Shah (b) (4)	09 Oct 2020 23:40:01
	(b) (4)	

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2016'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2016'	System	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2016'	System	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:40:01

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation chronic - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Oct 2020 23:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:41:45
Data point term sent to Coder	System	09 Oct 2020 23:40:21
User entered 'chronic constipation'	Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2013'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2013'	System	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2013'	System	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:40:17

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal crampy pains - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Oct 2020 03:41:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 03:41:21
Data point term sent to Coder	System	09 Oct 2020 23:41:23
User entered 'abdominal cramp pain'	Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2010'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2010'	System	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2010'	System	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:40:33

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Endometrial ablation, LLT: Uterine ablation - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Oct 2020 23:42:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 23:42:53
Data point term sent to Coder	System	09 Oct 2020 23:41:22
User entered 'uterine ablation'	Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2001'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2004'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2001'	System	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2001'	System	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2004'	System	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:33:37
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:54:13
User entered '2004'	System	09 Oct 2020 23:41:00

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Reproductive system and breast disorders, HLG: Vulvovaginal disorders (excl infections and inflammations), HLT: Vulvovaginal disorders NEC, PT: Vaginal haemorrhage, LLT: Vaginal bleeding - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 03:41:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 03:41:20
Data point term sent to Coder	System	09 Oct 2020 23:42:23
User entered 'accessibe vaginal bleeding'	Dhwani Shah (b) (4)	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2004'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2004'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2004'	System	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2004'	System	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2004'	System	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2004'	System	09 Oct 2020 23:41:23

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 23:58:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 23:58:05
Data point term sent to Coder	System	09 Oct 2020 23:56:30
User entered 'vitamin D deficiency'	Dhwani Shah (b) (4)	09 Oct 2020 23:56:18
	(b) (4)	

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2013'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2013'	System	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2013'	System	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:56:18

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
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)	05 Nov 2020 12:23:58
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 'confirmed as it is' (Site from DM).	Dhwani Shah (b) (4)	31 Oct 2020 00:08:58
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 Oct 2020 14:55:20
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 23:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 23:59:00
Data point term sent to Coder	System	09 Oct 2020 23:57:30
User entered 'hypothyroidism'	Dhwani Shah (b) (4)	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2013'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2013'	System	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2013'	System	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:56:36

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Oct 2020 23:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:59:00
Data point term sent to Coder	System	09 Oct 2020 23:57:30
User entered 'sleep apnea'	Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2015'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2015'	System	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2015'	System	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:56:48

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
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)	09 Oct 2020 23:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:59:00
Data point term sent to Coder	System	09 Oct 2020 23:57:30
User entered 'seasonal allergies'	Dhwani Shah (b) (4)	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 1970'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 1970'	System	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '1970'	System	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:57:00

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Drug withdrawal headache, LLT: Headache drug withdrawal - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Nov 2020 12:42:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 12:42:33
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Drug withdrawal headache, LLT: Headache drug withdrawal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:06:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:06:25
Data point term sent to Coder	System	09 Oct 2020 23:58:31
User entered 'HEADACHES CAFFIENE WITHDRAWAL' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:41
Data point term sent to Coder	System	09 Oct 2020 23:57:30
User entered 'headaches'	Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'un UNK 2017'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2017'	System	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2017'	System	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	09 Oct 2020 23:57:13

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Jan 2021 22:59:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 22:59:57
Data point term sent to Coder	System	25 Jan 2021 22:59:28
User entered 'DIVERTICULITIS'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'UN UNK 2013'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'Jan 2013'	System	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '2013'	System	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	25 Jan 2021 22:58:51

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '10:54'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '1 Oct 2020 10:54'	System	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '66' in	(b) (4) Dhwani Shah (b) (4)	03 Oct 2020 15:57:17
DataPoint set to visible.	(b) (4) System	01 Oct 2020 18:42:03

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '317' lb	(b) (4) Dhwani Shah (b) (4)	03 Oct 2020 15:57:17
DataPoint set to visible.	(b) (4) System	01 Oct 2020 18:42:03

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '51.27212'	System	03 Oct 2020 15:57:17
DataPoint set to visible.	System	01 Oct 2020 18:42:03

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'kg/m2'	System	03 Oct 2020 15:57:17
DataPoint set to visible.	System	01 Oct 2020 18:42:03

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '98.3' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'bpm'	System	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'breaths/min'	System	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'mmHg'	System	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'mmHg'	System	03 Oct 2020 15:57:17

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47

US3562205

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47

US3562205

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:56:19

US3562205

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:56:19

US3562205

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:03

US3562205

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:03

US3562205

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:36

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:03

US3562205

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:36

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:03

US3562205

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:03

US3562205

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:36

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:03

US3562205

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:03

US3562205

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:36

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:03

US3562205

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:16

US3562205

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:16

US3562205

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Urine (URINE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:16

US3562205

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Negative (NEGATIVE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:16

US3562205

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:16

US3562205

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:16

US3562205

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:58:16

US3562205

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	03 Oct 2020 15:58:16

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:15

US3562205

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:31

US3562205

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:31

US3562205

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:31

US3562205

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'VISIT1'	System	03 Oct 2020 15:59:31

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 18:13:01

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '146851'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 18:13:01

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Oct 2020 18:13:01

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:50

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:50

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:50

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:50

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:50

US3562205

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4)	03 Oct 2020 15:59:50
DataPoint set to visible.	(b) (4) System	01 Oct 2020 18:41:56

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '10:54'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '1 Oct 2020 10:54'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '98.3' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '67'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'bpm'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'breaths/min'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '140'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '88'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '12:08'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '1 Oct 2020 12:08'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '97.6' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '64'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'bpm'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'breaths/min'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '153'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '92'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	03 Oct 2020 16:03:08

US3562205

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:01

US3562205

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:01

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:08

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:08

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:08

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:08

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:08

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:08

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:02:08

US3562205

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered empty.	System	03 Oct 2020 16:02:08

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '11:37'	(b) (4), (b) (6)	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '1 Oct 2020 11:37'	System	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'ONCE'	System	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 18:42:40

US3562205

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:51

US3562205

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:51

US3562205

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '11:15'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:51

US3562205

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '1 Oct 2020 11:15'	System	03 Oct 2020 16:01:51

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:13:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '11:20'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '1 Oct 2020 11:20'	System	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered empty.	System	03 Oct 2020 16:01:38

US3562205

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 15:59:56

US3562205

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'I'	System	03 Oct 2020 15:59:56

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:13:10', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ea718a5b-0302-4346-a979-04412c0d0daa'	System	01 Oct 2020 19:11:10
User entered 'Yes (Y)'	System	01 Oct 2020 19:11:10

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:13:17', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ea718a5b-0302-4346-a979-04412c0d0daa'	System	01 Oct 2020 19:11:10
User entered '97.6'	System	01 Oct 2020 19:11:10

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:13:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ea718a5b-0302-4346-a979-04412c0d0daa'	System	01 Oct 2020 19:11:10
User entered 'No (N)'	System	01 Oct 2020 19:11:10

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:13:43', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ea718a5b-0302-4346-a979-04412c0d0daa'	System	01 Oct 2020 19:11:10
User entered '01 Oct 2020 12:13'	System	01 Oct 2020 19:11:10

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 11:57'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 14:27'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T22:59:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '994a8526-f1ac-4349-a291-23f5f118931f'	System	02 Oct 2020 05:57:13
User entered 'Yes (Y)'	System	02 Oct 2020 05:57:13

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T22:59:34', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '994a8526-f1ac-4349-a291-23f5f118931f' User entered '98.9'	System	02 Oct 2020 05:57:13

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T22:59:38', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '994a8526-f1ac-4349-a291-23f5f118931f'	System	02 Oct 2020 05:57:13
User entered 'No (N)'	System	02 Oct 2020 05:57:13

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T22:59:45', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '994a8526-f1ac-4349-a291-23f5f118931f'	System	02 Oct 2020 05:57:13
User entered '01 Oct 2020 22:59'	System	02 Oct 2020 05:57:13

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 15:22'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 2'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:51:42', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '45f3544d-7721-4705-88ba-ef2d3a1713c8'	System	03 Oct 2020 01:49:28
User entered 'Yes (Y)'	System	03 Oct 2020 01:49:28

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:51:52', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '45f3544d-7721-4705-88ba-ef2d3a1713c8'	System	03 Oct 2020 01:49:28
User entered '98.2'	System	03 Oct 2020 01:49:28

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:51:56', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '45f3544d-7721-4705-88ba-ef2d3a1713c8'	System	03 Oct 2020 01:49:28
User entered 'No (N)'	System	03 Oct 2020 01:49:28

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:52:01', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '45f3544d-7721-4705-88ba-ef2d3a1713c8'	System	03 Oct 2020 01:49:28
User entered '02 Oct 2020 18:52'	System	03 Oct 2020 01:49:28

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 3'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c01417c3-2887-4d43-936a-0c76fb99c719'	System	04 Oct 2020 02:37:00
User entered 'Yes (Y)'	System	04 Oct 2020 02:37:00

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:11', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c01417c3-2887-4d43-936a-0c76fb99c719'	System	04 Oct 2020 02:37:00
User entered '99.0'	System	04 Oct 2020 02:37:00

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:19', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c01417c3-2887-4d43-936a-0c76fb99c719'	System	04 Oct 2020 02:37:00
User entered 'Yes (Y)'	System	04 Oct 2020 02:37:00

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'sw pt and updated con med line 2' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 04:47:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Dhwani Shah (b) (4)	14 Oct 2020 22:11:55
and updated con med line 2' (Site from System).	(b) (4)	
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Oct 2020 02:37:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:25', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c01417c3-2887-4d43-936a-0c76fb99c719'	System	04 Oct 2020 02:37:00
User entered '1'	System	04 Oct 2020 02:37:00

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:25', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c01417c3-2887-4d43-936a-0c76fb99c719'	System	04 Oct 2020 02:37:00
User entered '0'	System	04 Oct 2020 02:37:00

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:33', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c01417c3-2887-4d43-936a-0c76fb99c719'	System	04 Oct 2020 02:37:00
User entered '03 Oct 2020 19:39'	System	04 Oct 2020 02:37:00

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 4'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:16', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6d5992fb-9d1a-4147-816c-36e6ff74d673'	System	05 Oct 2020 01:26:53
User entered 'Yes (Y)'	System	05 Oct 2020 01:26:53

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:20', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6d5992fb-9d1a-4147-816c-36e6ff74d673'	System	05 Oct 2020 01:26:53
User entered '98.6'	System	05 Oct 2020 01:26:53

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6d5992fb-9d1a-4147-816c-36e6ff74d673'	System	05 Oct 2020 01:26:53
User entered 'No (N)'	System	05 Oct 2020 01:26:53

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:27', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6d5992fb-9d1a-4147-816c-36e6ff74d673'	System	05 Oct 2020 01:26:53
User entered '04 Oct 2020 18:29'	System	05 Oct 2020 01:26:53

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 5'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:18', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fc416352-a77d-41a4-b26c-b864ee4add2a'	System	06 Oct 2020 01:01:55
User entered 'Yes (Y)'	System	06 Oct 2020 01:01:55

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:22', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fc416352-a77d-41a4-b26c-b864ee4add2a'	System	06 Oct 2020 01:01:55
User entered '99.0'	System	06 Oct 2020 01:01:55

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:24', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fc416352-a77d-41a4-b26c-b864ee4add2a'	System	06 Oct 2020 01:01:55
User entered 'No (N)'	System	06 Oct 2020 01:01:55

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:28', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fc416352-a77d-41a4-b26c-b864ee4add2a'	System	06 Oct 2020 01:01:55
User entered '05 Oct 2020 18:04'	System	06 Oct 2020 01:01:55

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 6'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:32', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1a8fad12-cd3c-4c69-9b45-ff4ffcef4f25'	System	07 Oct 2020 00:59:12
User entered 'Yes (Y)'	System	07 Oct 2020 00:59:12

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:38', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1a8fad12-cd3c-4c69-9b45-ff4ffcef4f25'	System	07 Oct 2020 00:59:12
User entered '98.8'	System	07 Oct 2020 00:59:12

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:42', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1a8fad12-cd3c-4c69-9b45-ff4ffcef4f25'	System	07 Oct 2020 00:59:12
User entered 'No (N)'	System	07 Oct 2020 00:59:12

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:45', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1a8fad12-cd3c-4c69-9b45-ff4ffcef4f25'	System	07 Oct 2020 00:59:12
User entered '06 Oct 2020 18:01'	System	07 Oct 2020 00:59:12

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 7'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:03', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '86b368c2-6aa5-49bd-87c9-998eabb213b7'	System	08 Oct 2020 01:54:40
User entered 'Yes (Y)'	System	08 Oct 2020 01:54:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:07', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '86b368c2-6aa5-49bd-87c9-998eabb213b7'	System	08 Oct 2020 01:54:40
User entered '98.6'	System	08 Oct 2020 01:54:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:10', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '86b368c2-6aa5-49bd-87c9-998eabb213b7'	System	08 Oct 2020 01:54:40
User entered 'No (N)'	System	08 Oct 2020 01:54:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:13', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '86b368c2-6aa5-49bd-87c9-998eabb213b7'	System	08 Oct 2020 01:54:40
User entered '07 Oct 2020 18:57'	System	08 Oct 2020 01:54:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:13:58', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '092d7dce-de18-4b0d-9809-161bdc8dd859'	System	01 Oct 2020 19:11:49
User entered 'None (1)'	System	01 Oct 2020 19:11:49

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:14:08', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '092d7dce-de18-4b0d-9809-161bdc8dd859'	System	01 Oct 2020 19:11:49
User entered 'No (N)'	System	01 Oct 2020 19:11:49

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:14:13', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '092d7dce-de18-4b0d-9809-161bdc8dd859'	System	01 Oct 2020 19:11:49
User entered 'No (N)'	System	01 Oct 2020 19:11:49

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:14:17', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '092d7dce-de18-4b0d-9809-161bdc8dd859'	System	01 Oct 2020 19:11:49
User entered 'None (1)'	System	01 Oct 2020 19:11:49

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:14:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '092d7dce-de18-4b0d-9809-161bdc8dd859'	System	01 Oct 2020 19:11:49
User entered '01 Oct 2020 12:14'	System	01 Oct 2020 19:11:49

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 11:57'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 14:27'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T22:59:53', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339a9450-f953-48d7-b045-049e59b32be9'	System	02 Oct 2020 05:58:05
User entered 'None (1)'	System	02 Oct 2020 05:58:05

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:14', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339a9450-f953-48d7-b045-049e59b32be9'	System	02 Oct 2020 05:58:05
User entered 'No (N)'	System	02 Oct 2020 05:58:05

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:22', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339a9450-f953-48d7-b045-049e59b32be9'	System	02 Oct 2020 05:58:05
User entered 'No (N)'	System	02 Oct 2020 05:58:05

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:33', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339a9450-f953-48d7-b045-049e59b32be9'	System	02 Oct 2020 05:58:05
User entered 'None (1)'	System	02 Oct 2020 05:58:05

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:39', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339a9450-f953-48d7-b045-049e59b32be9'	System	02 Oct 2020 05:58:05
User entered '01 Oct 2020 23:00'	System	02 Oct 2020 05:58:05

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 15:22'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 2'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:52:14', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '77ddaa5e-4d5d-428e-8802-cbcfb63753cb'	System	03 Oct 2020 01:50:17
User entered 'None (1)'	System	03 Oct 2020 01:50:17

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:52:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '77ddaa5e-4d5d-428e-8802-cbcfb63753cb'	System	03 Oct 2020 01:50:17
User entered 'No (N)'	System	03 Oct 2020 01:50:17

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:52:32', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '77ddaa5e-4d5d-428e-8802-cbcfb63753cb'	System	03 Oct 2020 01:50:17
User entered 'No (N)'	System	03 Oct 2020 01:50:17

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:52:42', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '77ddaa5e-4d5d-428e-8802-cbcfb63753cb'	System	03 Oct 2020 01:50:17
User entered 'None (1)'	System	03 Oct 2020 01:50:17

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:52:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '77ddaa5e-4d5d-428e-8802-cbcfb63753cb'	System	03 Oct 2020 01:50:17
User entered '02 Oct 2020 18:52'	System	03 Oct 2020 01:50:17

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 3'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:44', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fd324240-4ab3-42c2-aae9-128002c3533b'	System	04 Oct 2020 02:37:35
User entered 'None (1)'	System	04 Oct 2020 02:37:35

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fd324240-4ab3-42c2-aae9-128002c3533b'	System	04 Oct 2020 02:37:35
User entered 'No (N)'	System	04 Oct 2020 02:37:35

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:39:51', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fd324240-4ab3-42c2-aae9-128002c3533b'	System	04 Oct 2020 02:37:35
User entered 'No (N)'	System	04 Oct 2020 02:37:35

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:02', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fd324240-4ab3-42c2-aae9-128002c3533b'	System	04 Oct 2020 02:37:35
User entered 'None (1)'	System	04 Oct 2020 02:37:35

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'fd324240-4ab3-42c2-aae9-128002c3533b'	System	04 Oct 2020 02:37:35
User entered '03 Oct 2020 19:40'	System	04 Oct 2020 02:37:35

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 4'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:32', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4baf3b62-e9c6-48da-a944-942519b04ba0'	System	05 Oct 2020 01:27:23
User entered 'None (1)'	System	05 Oct 2020 01:27:23

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:37', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4baf3b62-e9c6-48da-a944-942519b04ba0'	System	05 Oct 2020 01:27:23
User entered 'No (N)'	System	05 Oct 2020 01:27:23

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:40', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4baf3b62-e9c6-48da-a944-942519b04ba0'	System	05 Oct 2020 01:27:23
User entered 'No (N)'	System	05 Oct 2020 01:27:23

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:49', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4baf3b62-e9c6-48da-a944-942519b04ba0'	System	05 Oct 2020 01:27:23
User entered 'None (1)'	System	05 Oct 2020 01:27:23

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:29:56', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4baf3b62-e9c6-48da-a944-942519b04ba0'	System	05 Oct 2020 01:27:23
User entered '04 Oct 2020 18:29'	System	05 Oct 2020 01:27:23

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 5'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:32', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'bd9d2168-6651-4fbe-bcec-d8c3cf6c655c'	System	06 Oct 2020 01:02:15
User entered 'None (1)'	System	06 Oct 2020 01:02:15

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:35', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'bd9d2168-6651-4fbe-bcec-d8c3cf6c655c'	System	06 Oct 2020 01:02:15
User entered 'No (N)'	System	06 Oct 2020 01:02:15

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:38', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'bd9d2168-6651-4fbe-bcec-d8c3cf6c655c'	System	06 Oct 2020 01:02:15
User entered 'No (N)'	System	06 Oct 2020 01:02:15

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:44', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'bd9d2168-6651-4fbe-bcec-d8c3cf6c655c'	System	06 Oct 2020 01:02:15
User entered 'None (1)'	System	06 Oct 2020 01:02:15

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:47', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'bd9d2168-6651-4fbe-bcec-d8c3cf6c655c'	System	06 Oct 2020 01:02:15
User entered '05 Oct 2020 18:04'	System	06 Oct 2020 01:02:15

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 6'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '0e1ce9f9-3932-4695-ab6d-b3802975309d'	System	07 Oct 2020 00:59:24
User entered 'None (1)'	System	07 Oct 2020 00:59:24

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:51', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '0e1ce9f9-3932-4695-ab6d-b3802975309d'	System	07 Oct 2020 00:59:24
User entered 'No (N)'	System	07 Oct 2020 00:59:24

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:53', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '0e1ce9f9-3932-4695-ab6d-b3802975309d'	System	07 Oct 2020 00:59:24
User entered 'No (N)'	System	07 Oct 2020 00:59:24

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:55', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '0e1ce9f9-3932-4695-ab6d-b3802975309d'	System	07 Oct 2020 00:59:24
User entered 'None (1)'	System	07 Oct 2020 00:59:24

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:01:58', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '0e1ce9f9-3932-4695-ab6d-b3802975309d'	System	07 Oct 2020 00:59:24
User entered '06 Oct 2020 18:01'	System	07 Oct 2020 00:59:24

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 7'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:18', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1e8ab637-57f4-49c4-897d-218893efe95d'	System	08 Oct 2020 01:54:57
User entered 'None (1)'	System	08 Oct 2020 01:54:57

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:21', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1e8ab637-57f4-49c4-897d-218893efe95d'	System	08 Oct 2020 01:54:57
User entered 'No (N)'	System	08 Oct 2020 01:54:57

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1e8ab637-57f4-49c4-897d-218893efe95d'	System	08 Oct 2020 01:54:57
User entered 'No (N)'	System	08 Oct 2020 01:54:57

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:26', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1e8ab637-57f4-49c4-897d-218893efe95d'	System	08 Oct 2020 01:54:57
User entered 'None (1)'	System	08 Oct 2020 01:54:57

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:30', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1e8ab637-57f4-49c4-897d-218893efe95d'	System	08 Oct 2020 01:54:57
User entered '07 Oct 2020 18:57'	System	08 Oct 2020 01:54:57

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:14:35', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd17b0aa1-6dcd-42a1-82ed-915e98b403a5'	System	01 Oct 2020 19:12:55
User entered 'None (0)'	System	01 Oct 2020 19:12:55

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:14:39', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd17b0aa1-6dcd-42a1-82ed-915e98b403a5'	System	01 Oct 2020 19:12:55
User entered 'None (0)'	System	01 Oct 2020 19:12:55

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:14:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd17b0aa1-6dcd-42a1-82ed-915e98b403a5'	System	01 Oct 2020 19:12:55
User entered 'None (0)'	System	01 Oct 2020 19:12:55

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:15:02', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd17b0aa1-6dcd-42a1-82ed-915e98b403a5'	System	01 Oct 2020 19:12:55
User entered 'None (0)'	System	01 Oct 2020 19:12:55

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:15:17', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd17b0aa1-6dcd-42a1-82ed-915e98b403a5'	System	01 Oct 2020 19:12:55
User entered 'None (0)'	System	01 Oct 2020 19:12:55

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:15:20', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd17b0aa1-6dcd-42a1-82ed-915e98b403a5'	System	01 Oct 2020 19:12:55
User entered 'None (0)'	System	01 Oct 2020 19:12:55

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:15:25', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd17b0aa1-6dcd-42a1-82ed-915e98b403a5'	System	01 Oct 2020 19:12:55
User entered 'No (N)'	System	01 Oct 2020 19:12:55

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T12:15:29', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd17b0aa1-6dcd-42a1-82ed-915e98b403a5'	System	01 Oct 2020 19:12:55
User entered '01 Oct 2020 12:15'	System	01 Oct 2020 19:12:55

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 11:57'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 14:27'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:45', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '53309155-4481-4190-ac70-8a36fde57bfd'	System	02 Oct 2020 05:58:40
User entered 'None (0)'	System	02 Oct 2020 05:58:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '53309155-4481-4190-ac70-8a36fde57bfd'	System	02 Oct 2020 05:58:40
User entered 'None (0)'	System	02 Oct 2020 05:58:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:50', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '53309155-4481-4190-ac70-8a36fde57bfd'	System	02 Oct 2020 05:58:40
User entered 'None (0)'	System	02 Oct 2020 05:58:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:55', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '53309155-4481-4190-ac70-8a36fde57bfd'	System	02 Oct 2020 05:58:40
User entered 'None (0)'	System	02 Oct 2020 05:58:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:00:59', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '53309155-4481-4190-ac70-8a36fde57bfd'	System	02 Oct 2020 05:58:40
User entered 'None (0)'	System	02 Oct 2020 05:58:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:01:01', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '53309155-4481-4190-ac70-8a36fde57bfd'	System	02 Oct 2020 05:58:40
User entered 'None (0)'	System	02 Oct 2020 05:58:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:01:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '53309155-4481-4190-ac70-8a36fde57bfd'	System	02 Oct 2020 05:58:40
User entered 'No (N)'	System	02 Oct 2020 05:58:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-01T23:01:12', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '53309155-4481-4190-ac70-8a36fde57bfd'	System	02 Oct 2020 05:58:40
User entered '01 Oct 2020 23:01'	System	02 Oct 2020 05:58:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Oct 2020 15:22'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 2'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:52:53', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '39b928c5-8718-413c-8eed-2d1919f48384'	System	03 Oct 2020 01:50:52
User entered 'None (0)'	System	03 Oct 2020 01:50:52

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:52:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '39b928c5-8718-413c-8eed-2d1919f48384'	System	03 Oct 2020 01:50:52
User entered 'None (0)'	System	03 Oct 2020 01:50:52

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:53:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '39b928c5-8718-413c-8eed-2d1919f48384'	System	03 Oct 2020 01:50:52
User entered 'None (0)'	System	03 Oct 2020 01:50:52

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:53:03', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '39b928c5-8718-413c-8eed-2d1919f48384'	System	03 Oct 2020 01:50:52
User entered 'None (0)'	System	03 Oct 2020 01:50:52

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:53:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '39b928c5-8718-413c-8eed-2d1919f48384'	System	03 Oct 2020 01:50:52
User entered 'None (0)'	System	03 Oct 2020 01:50:52

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:53:08', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '39b928c5-8718-413c-8eed-2d1919f48384'	System	03 Oct 2020 01:50:52
User entered 'None (0)'	System	03 Oct 2020 01:50:52

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:53:14', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '39b928c5-8718-413c-8eed-2d1919f48384'	System	03 Oct 2020 01:50:52
User entered 'No (N)'	System	03 Oct 2020 01:50:52

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-02T18:53:26', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '39b928c5-8718-413c-8eed-2d1919f48384'	System	03 Oct 2020 01:50:52
User entered '02 Oct 2020 18:53'	System	03 Oct 2020 01:50:52

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 3'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c98a2cf5-772f-4274-898f-6ff1a33f8bd5'	System	04 Oct 2020 02:38:25
User entered 'No interference with activity (1)'	System	04 Oct 2020 02:38:25

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:29', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c98a2cf5-772f-4274-898f-6ff1a33f8bd5'	System	04 Oct 2020 02:38:25
User entered 'None (0)'	System	04 Oct 2020 02:38:25

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:31', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c98a2cf5-772f-4274-898f-6ff1a33f8bd5'	System	04 Oct 2020 02:38:25
User entered 'None (0)'	System	04 Oct 2020 02:38:25

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:35', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c98a2cf5-772f-4274-898f-6ff1a33f8bd5'	System	04 Oct 2020 02:38:25
User entered 'None (0)'	System	04 Oct 2020 02:38:25

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:39', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c98a2cf5-772f-4274-898f-6ff1a33f8bd5'	System	04 Oct 2020 02:38:25
User entered 'None (0)'	System	04 Oct 2020 02:38:25

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:42', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c98a2cf5-772f-4274-898f-6ff1a33f8bd5'	System	04 Oct 2020 02:38:25
User entered 'None (0)'	System	04 Oct 2020 02:38:25

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:47', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c98a2cf5-772f-4274-898f-6ff1a33f8bd5'	System	04 Oct 2020 02:38:25
User entered 'No (N)'	System	04 Oct 2020 02:38:25

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-03T19:40:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c98a2cf5-772f-4274-898f-6ff1a33f8bd5'	System	04 Oct 2020 02:38:25
User entered '03 Oct 2020 19:40'	System	04 Oct 2020 02:38:25

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 4'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:30:01', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '961b9466-75b5-4419-93f5-fc9012a9c2c8'	System	05 Oct 2020 01:27:51
User entered 'None (0)'	System	05 Oct 2020 01:27:51

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:30:03', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '961b9466-75b5-4419-93f5-fc9012a9c2c8'	System	05 Oct 2020 01:27:51
User entered 'None (0)'	System	05 Oct 2020 01:27:51

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:30:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '961b9466-75b5-4419-93f5-fc9012a9c2c8'	System	05 Oct 2020 01:27:51
User entered 'None (0)'	System	05 Oct 2020 01:27:51

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:30:09', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '961b9466-75b5-4419-93f5-fc9012a9c2c8'	System	05 Oct 2020 01:27:51
User entered 'None (0)'	System	05 Oct 2020 01:27:51

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:30:11', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '961b9466-75b5-4419-93f5-fc9012a9c2c8'	System	05 Oct 2020 01:27:51
User entered 'None (0)'	System	05 Oct 2020 01:27:51

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:30:13', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '961b9466-75b5-4419-93f5-fc9012a9c2c8'	System	05 Oct 2020 01:27:51
User entered 'None (0)'	System	05 Oct 2020 01:27:51

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:30:21', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '961b9466-75b5-4419-93f5-fc9012a9c2c8'	System	05 Oct 2020 01:27:51
User entered 'No (N)'	System	05 Oct 2020 01:27:51

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-04T18:30:25', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '961b9466-75b5-4419-93f5-fc9012a9c2c8'	System	05 Oct 2020 01:27:51
User entered '04 Oct 2020 18:30'	System	05 Oct 2020 01:27:51

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 5'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:51', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1273136-7bee-4950-a6c6-4cec9cafa3ad'	System	06 Oct 2020 01:02:35
User entered 'None (0)'	System	06 Oct 2020 01:02:35

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:53', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1273136-7bee-4950-a6c6-4cec9cafa3ad'	System	06 Oct 2020 01:02:35
User entered 'None (0)'	System	06 Oct 2020 01:02:35

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:55', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1273136-7bee-4950-a6c6-4cec9cafa3ad'	System	06 Oct 2020 01:02:35
User entered 'None (0)'	System	06 Oct 2020 01:02:35

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1273136-7bee-4950-a6c6-4cec9cafa3ad'	System	06 Oct 2020 01:02:35
User entered 'None (0)'	System	06 Oct 2020 01:02:35

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:04:58', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1273136-7bee-4950-a6c6-4cec9cafa3ad'	System	06 Oct 2020 01:02:35
User entered 'None (0)'	System	06 Oct 2020 01:02:35

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:05:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1273136-7bee-4950-a6c6-4cec9cafa3ad'	System	06 Oct 2020 01:02:35
User entered 'None (0)'	System	06 Oct 2020 01:02:35

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:05:04', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1273136-7bee-4950-a6c6-4cec9cafa3ad'	System	06 Oct 2020 01:02:35
User entered 'No (N)'	System	06 Oct 2020 01:02:35

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-05T18:05:07', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1273136-7bee-4950-a6c6-4cec9cafa3ad'	System	06 Oct 2020 01:02:35
User entered '05 Oct 2020 18:05'	System	06 Oct 2020 01:02:35

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 6'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:02:03', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '218b9e86-da1b-4c44-9fbd-827bcf4d2c2e'	System	07 Oct 2020 00:59:58
User entered 'None (0)'	System	07 Oct 2020 00:59:58

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:02:05', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '218b9e86-da1b-4c44-9fbd-827bcf4d2c2e'	System	07 Oct 2020 00:59:58
User entered 'None (0)'	System	07 Oct 2020 00:59:58

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:02:07', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '218b9e86-da1b-4c44-9fbd-827bcf4d2c2e'	System	07 Oct 2020 00:59:58
User entered 'None (0)'	System	07 Oct 2020 00:59:58

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:02:08', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '218b9e86-da1b-4c44-9fbd-827bcf4d2c2e'	System	07 Oct 2020 00:59:58
User entered 'None (0)'	System	07 Oct 2020 00:59:58

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:02:11', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '218b9e86-da1b-4c44-9fbd-827bcf4d2c2e'	System	07 Oct 2020 00:59:58
User entered 'None (0)'	System	07 Oct 2020 00:59:58

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:02:13', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '218b9e86-da1b-4c44-9fbd-827bcf4d2c2e'	System	07 Oct 2020 00:59:58
User entered 'None (0)'	System	07 Oct 2020 00:59:58

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:02:27', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '218b9e86-da1b-4c44-9fbd-827bcf4d2c2e'	System	07 Oct 2020 00:59:58
User entered 'No (N)'	System	07 Oct 2020 00:59:58

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-06T18:02:30', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '218b9e86-da1b-4c44-9fbd-827bcf4d2c2e'	System	07 Oct 2020 00:59:58
User entered '06 Oct 2020 18:02'	System	07 Oct 2020 00:59:58

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	01 Oct 2020 18:42:40
User entered 'Day 7'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:34', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '78b40828-cbc0-4011-baca-cc7d615aae6f'	System	08 Oct 2020 01:55:33
User entered 'None (0)'	System	08 Oct 2020 01:55:33

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:37', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '78b40828-cbc0-4011-baca-cc7d615aae6f'	System	08 Oct 2020 01:55:33
User entered 'None (0)'	System	08 Oct 2020 01:55:33

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:40', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '78b40828-cbc0-4011-baca-cc7d615aae6f'	System	08 Oct 2020 01:55:33
User entered 'None (0)'	System	08 Oct 2020 01:55:33

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:42', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '78b40828-cbc0-4011-baca-cc7d615aae6f'	System	08 Oct 2020 01:55:33
User entered 'None (0)'	System	08 Oct 2020 01:55:33

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:45', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '78b40828-cbc0-4011-baca-cc7d615aae6f'	System	08 Oct 2020 01:55:33
User entered 'None (0)'	System	08 Oct 2020 01:55:33

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:57:47', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '78b40828-cbc0-4011-baca-cc7d615aae6f'	System	08 Oct 2020 01:55:33
User entered 'None (0)'	System	08 Oct 2020 01:55:33

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:58:01', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '78b40828-cbc0-4011-baca-cc7d615aae6f'	System	08 Oct 2020 01:55:33
User entered 'No (N)'	System	08 Oct 2020 01:55:33

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-07T18:58:04', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '78b40828-cbc0-4011-baca-cc7d615aae6f'	System	08 Oct 2020 01:55:33
User entered '07 Oct 2020 18:58'	System	08 Oct 2020 01:55:33

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:42:40

US3562205

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:42:40

US3562205

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 00:25:06

US3562205

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '8 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 00:25:06

US3562205

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 00:25:06

US3562205

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 00:25:06

US3562205

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Oct 2020 00:25:14

US3562205

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'l'	System	09 Oct 2020 00:25:14

US3562205

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Oct 2020 13:45:44

US3562205

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Oct 2020 13:45:44

US3562205

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Oct 2020 13:45:44

US3562205

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Oct 2020 13:45:44

US3562205

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Oct 2020 13:45:48

US3562205

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'I'	System	16 Oct 2020 13:45:48

US3562205

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:44:04

US3562205

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '22 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:44:04

US3562205

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:44:04

US3562205

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:44:04

US3562205

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:44:07

US3562205

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'l'	System	22 Oct 2020 21:44:07

US3562205

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:44

US3562205

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:44

US3562205

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:44

US3562205

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'VISIT2'	System	29 Oct 2020 18:03:44

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '10:10'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '29 Oct 2020 10:10'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '98.8' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '71'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'bpm'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'breaths/min'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '146'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '87'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '11:26'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '29 Oct 2020 11:26'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '99.3' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '73'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'bpm'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'breaths/min'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '127'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '81'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	29 Oct 2020 19:45:14

US3562205

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	26 Feb 2021 15:19:52
User entered 'No (N)'	(b) (4)	
	Dhwani Shah (b) (4)	29 Oct 2020 19:43:56
	(b) (4)	

US3562205

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	26 Feb 2021 15:19:52
User entered empty.	(b) (4)	
	Dhwani Shah (b) (4)	29 Oct 2020 19:43:56
	(b) (4)	

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:57

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:57

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Urine (URINE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:57

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Negative (NEGATIVE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:57

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:57

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:57

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:57

US3562205

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered empty.	System	29 Oct 2020 18:03:57

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'MRNA-1273 OR PLACEBO'	System	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '10:55'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '29 Oct 2020 10:55'	System	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'ONCE'	System	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'INTRAMUSCULAR'	System	29 Oct 2020 18:03:23

US3562205

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:08

US3562205

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:08

US3562205

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '10:17'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:08

US3562205

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '29 Oct 2020 10:17'	System	29 Oct 2020 19:44:08

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:13:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '10:40'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '29 Oct 2020 10:40'	System	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered empty.	System	29 Oct 2020 19:44:22

US3562205

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 18:03:32

US3562205

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'I'	System	29 Oct 2020 18:03:32

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:30:44', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7cd2aeff-a485-4ed9-bfa2-353c8e78260d'	System	29 Oct 2020 18:28:05
User entered 'Yes (Y)'	System	29 Oct 2020 18:28:05

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:30:50', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7cd2aeff-a485-4ed9-bfa2-353c8e78260d'	System	29 Oct 2020 18:28:05
User entered '99.3'	System	29 Oct 2020 18:28:05

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:30:56', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7cd2aeff-a485-4ed9-bfa2-353c8e78260d'	System	29 Oct 2020 18:28:05
User entered 'No (N)'	System	29 Oct 2020 18:28:05

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:01', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7cd2aeff-a485-4ed9-bfa2-353c8e78260d'	System	29 Oct 2020 18:28:05
User entered '29 Oct 2020 11:31'	System	29 Oct 2020 18:28:05

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 11:15'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 13:45'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:21:34', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e5b4099c-3c56-491f-8dc2-d609c7716380'	System	30 Oct 2020 02:18:47
User entered 'Yes (Y)'	System	30 Oct 2020 02:18:47

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:21:38', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e5b4099c-3c56-491f-8dc2-d609c7716380' User entered '99.4'	System	30 Oct 2020 02:18:47
	System	30 Oct 2020 02:18:47

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:21:41', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e5b4099c-3c56-491f-8dc2-d609c7716380'	System	30 Oct 2020 02:18:47
User entered 'No (N)'	System	30 Oct 2020 02:18:47

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:21:44', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e5b4099c-3c56-491f-8dc2-d609c7716380'	System	30 Oct 2020 02:18:47
User entered '29 Oct 2020 19:21'	System	30 Oct 2020 02:18:47

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 14:40'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 2'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:11:31', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339ee574-f581-4ade-9297-70a58128f16e'	System	31 Oct 2020 02:08:53
User entered 'Yes (Y)'	System	31 Oct 2020 02:08:53

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:11:38', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339ee574-f581-4ade-9297-70a58128f16e' User entered '100.2'	System	31 Oct 2020 02:08:53
	System	31 Oct 2020 02:08:53

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:11:47', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339ee574-f581-4ade-9297-70a58128f16e'	System	31 Oct 2020 02:08:53
User entered 'No (N)'	System	31 Oct 2020 02:08:53

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:11:50', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '339ee574-f581-4ade-9297-70a58128f16e'	System	31 Oct 2020 02:08:53
User entered '30 Oct 2020 19:11'	System	31 Oct 2020 02:08:53

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 3'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:10:56', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4f79c00e-d9f2-4ff5-99a5-6414772eccc33'	System	01 Nov 2020 02:08:18
User entered 'Yes (Y)'	System	01 Nov 2020 02:08:18

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4f79c00e-d9f2-4ff5-99a5-6414772ece33'	System	01 Nov 2020 02:08:18
User entered '99.1'	System	01 Nov 2020 02:08:18

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:05', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4f79c00e-d9f2-4ff5-99a5-6414772eccc33'	System	01 Nov 2020 02:08:18
User entered 'Yes (Y)'	System	01 Nov 2020 02:08:18

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'sw pt and updated con med line 7*8' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 06:01:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'sw pt and updated con med line 7*8' (Site from System).	Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:58:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Nov 2020 02:08:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:10', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4f79c00e-d9f2-4ff5-99a5-6414772eccc33'	System	01 Nov 2020 02:08:18
User entered '1'	System	01 Nov 2020 02:08:18

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:10', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4f79c00e-d9f2-4ff5-99a5-6414772eccc33'	System	01 Nov 2020 02:08:18
User entered '0'	System	01 Nov 2020 02:08:18

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:14', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '4f79c00e-d9f2-4ff5-99a5-6414772eccc33'	System	01 Nov 2020 02:08:18
User entered '31 Oct 2020 19:11'	System	01 Nov 2020 02:08:18

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 4'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:06:26', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'cf2e30cf-00a4-4f24-b758-eac593f2f736'	System	02 Nov 2020 01:03:43
User entered 'Yes (Y)'	System	02 Nov 2020 01:03:43

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:06:31', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'cf2e30cf-00a4-4f24-b758-eac593f2f736'	System	02 Nov 2020 01:03:43
User entered '99.3'	System	02 Nov 2020 01:03:43

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:06:33', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'cf2e30cf-00a4-4f24-b758-eac593f2f736'	System	02 Nov 2020 01:03:43
User entered 'No (N)'	System	02 Nov 2020 01:03:43

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:06:36', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'cf2e30cf-00a4-4f24-b758-eac593f2f736'	System	02 Nov 2020 01:03:43
User entered '01 Nov 2020 18:06'	System	02 Nov 2020 01:03:43

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 5'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:52:33', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c5d1b359-75c0-412f-8d12-97ff12814de5'	System	03 Nov 2020 00:49:49
User entered 'Yes (Y)'	System	03 Nov 2020 00:49:49

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:52:39', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c5d1b359-75c0-412f-8d12-97ff12814de5'	System	03 Nov 2020 00:49:49
User entered '98.8'	System	03 Nov 2020 00:49:49

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:52:42', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c5d1b359-75c0-412f-8d12-97ff12814de5'	System	03 Nov 2020 00:49:49
User entered 'No (N)'	System	03 Nov 2020 00:49:49

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:52:46', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c5d1b359-75c0-412f-8d12-97ff12814de5'	System	03 Nov 2020 00:49:49
User entered '02 Nov 2020 17:52'	System	03 Nov 2020 00:49:49

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 6'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:22', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ab41e633-21e7-40ff-b49e-8fb6abdfdda5'	System	04 Nov 2020 04:50:38
User entered 'Yes (Y)'	System	04 Nov 2020 04:50:38

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:25', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ab41e633-21e7-40ff-b49e-8fb6abdfdda5'	System	04 Nov 2020 04:50:38
User entered '99.1'	System	04 Nov 2020 04:50:38

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:28', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ab41e633-21e7-40ff-b49e-8fb6abdfdda5'	System	04 Nov 2020 04:50:38
User entered 'No (N)'	System	04 Nov 2020 04:50:38

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:33', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ab41e633-21e7-40ff-b49e-8fb6abdfdda5'	System	04 Nov 2020 04:50:38
User entered '03 Nov 2020 21:53'	System	04 Nov 2020 04:50:38

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 7'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a25b8f67-4a1d-432a-b2fc-9edcd115c92f'	System	05 Nov 2020 05:14:28
User entered 'Yes (Y)'	System	05 Nov 2020 05:14:28

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:11', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a25b8f67-4a1d-432a-b2fc-9edcd115c92f'	System	05 Nov 2020 05:14:28
User entered '98.5'	System	05 Nov 2020 05:14:28

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:21', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a25b8f67-4a1d-432a-b2fc-9edcd115c92f'	System	05 Nov 2020 05:14:28
User entered 'No (N)'	System	05 Nov 2020 05:14:28

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:24', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a25b8f67-4a1d-432a-b2fc-9edcd115c92f'	System	05 Nov 2020 05:14:28
User entered '04 Nov 2020 22:17'	System	05 Nov 2020 05:14:28

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:08', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7e55a4b7-51aa-46df-ada0-0e95c4bfe1af'	System	29 Oct 2020 18:28:44
User entered 'None (1)'	System	29 Oct 2020 18:28:44

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:22', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7e55a4b7-51aa-46df-ada0-0e95c4bfe1af'	System	29 Oct 2020 18:28:44
User entered 'No (N)'	System	29 Oct 2020 18:28:44

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:27', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7e55a4b7-51aa-46df-ada0-0e95c4bfe1af'	System	29 Oct 2020 18:28:44
User entered 'No (N)'	System	29 Oct 2020 18:28:44

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:36', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7e55a4b7-51aa-46df-ada0-0e95c4bfe1af'	System	29 Oct 2020 18:28:44
User entered 'None (1)'	System	29 Oct 2020 18:28:44

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:41', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '7e55a4b7-51aa-46df-ada0-0e95c4bfe1af'	System	29 Oct 2020 18:28:44
User entered '29 Oct 2020 11:31'	System	29 Oct 2020 18:28:44

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 11:15'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 13:45'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:21:47', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3361eeeb-f865-4e2c-b7be-e80534ea95ce'	System	30 Oct 2020 02:19:10
User entered 'None (1)'	System	30 Oct 2020 02:19:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:21:56', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3361eeeb-f865-4e2c-b7be-e80534ea95ce'	System	30 Oct 2020 02:19:10
User entered 'No (N)'	System	30 Oct 2020 02:19:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:21:58', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3361eeeb-f865-4e2c-b7be-e80534ea95ce'	System	30 Oct 2020 02:19:10
User entered 'No (N)'	System	30 Oct 2020 02:19:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:01', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3361eeeb-f865-4e2c-b7be-e80534ea95ce'	System	30 Oct 2020 02:19:10
User entered 'None (1)'	System	30 Oct 2020 02:19:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3361eeeb-f865-4e2c-b7be-e80534ea95ce'	System	30 Oct 2020 02:19:10
User entered '29 Oct 2020 19:22'	System	30 Oct 2020 02:19:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 14:40'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 2'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:11:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a9efc849-3cdc-4624-976a-c0d146afcea6'	System	31 Oct 2020 02:09:28
User entered 'Does not interfere with activity (2)'	System	31 Oct 2020 02:09:28

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a9efc849-3cdc-4624-976a-c0d146afcea6'	System	31 Oct 2020 02:09:28
User entered 'No (N)'	System	31 Oct 2020 02:09:28

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:16', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a9efc849-3cdc-4624-976a-c0d146afcea6'	System	31 Oct 2020 02:09:28
User entered 'No (N)'	System	31 Oct 2020 02:09:28

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:22', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a9efc849-3cdc-4624-976a-c0d146afcea6'	System	31 Oct 2020 02:09:28
User entered 'None (1)'	System	31 Oct 2020 02:09:28

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:25', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a9efc849-3cdc-4624-976a-c0d146afcea6'	System	31 Oct 2020 02:09:28
User entered '30 Oct 2020 19:12'	System	31 Oct 2020 02:09:28

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 3'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:19', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8683c407-629d-48f7-b0fb-0a8464a872ed'	System	01 Nov 2020 02:08:41
User entered 'Does not interfere with activity (2)'	System	01 Nov 2020 02:08:41

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:22', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8683c407-629d-48f7-b0fb-0a8464a872ed'	System	01 Nov 2020 02:08:41
User entered 'No (N)'	System	01 Nov 2020 02:08:41

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:25', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8683c407-629d-48f7-b0fb-0a8464a872ed'	System	01 Nov 2020 02:08:41
User entered 'No (N)'	System	01 Nov 2020 02:08:41

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:31', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8683c407-629d-48f7-b0fb-0a8464a872ed'	System	01 Nov 2020 02:08:41
User entered 'None (1)'	System	01 Nov 2020 02:08:41

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:34', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8683c407-629d-48f7-b0fb-0a8464a872ed'	System	01 Nov 2020 02:08:41
User entered '31 Oct 2020 19:11'	System	01 Nov 2020 02:08:41

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 4'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:06:43', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1d007ae-e88d-4c17-9703-091c661a7c62'	System	02 Nov 2020 01:04:10
User entered 'Does not interfere with activity (2)'	System	02 Nov 2020 01:04:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:06:46', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1d007ae-e88d-4c17-9703-091c661a7c62'	System	02 Nov 2020 01:04:10
User entered 'No (N)'	System	02 Nov 2020 01:04:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:06:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1d007ae-e88d-4c17-9703-091c661a7c62'	System	02 Nov 2020 01:04:10
User entered 'No (N)'	System	02 Nov 2020 01:04:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:06:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1d007ae-e88d-4c17-9703-091c661a7c62'	System	02 Nov 2020 01:04:10
User entered 'None (1)'	System	02 Nov 2020 01:04:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd1d007ae-e88d-4c17-9703-091c661a7c62'	System	02 Nov 2020 01:04:10
User entered '01 Nov 2020 18:07'	System	02 Nov 2020 01:04:10

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 5'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:52:52', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'dc4d4bdd-8b57-45ed-bfe0-9aa92cd569d0'	System	03 Nov 2020 00:50:11
User entered 'None (1)'	System	03 Nov 2020 00:50:11

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:52:56', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'dc4d4bdd-8b57-45ed-bfe0-9aa92cd569d0'	System	03 Nov 2020 00:50:11
User entered 'No (N)'	System	03 Nov 2020 00:50:11

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:52:58', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'dc4d4bdd-8b57-45ed-bfe0-9aa92cd569d0'	System	03 Nov 2020 00:50:11
User entered 'No (N)'	System	03 Nov 2020 00:50:11

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:04', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'dc4d4bdd-8b57-45ed-bfe0-9aa92cd569d0'	System	03 Nov 2020 00:50:11
User entered 'None (1)'	System	03 Nov 2020 00:50:11

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:07', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'dc4d4bdd-8b57-45ed-bfe0-9aa92cd569d0'	System	03 Nov 2020 00:50:11
User entered '02 Nov 2020 17:53'	System	03 Nov 2020 00:50:11

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 6'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:38', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8128710a-46d2-4974-a6e1-ca8d6a39ade1'	System	04 Nov 2020 04:51:00
User entered 'None (1)'	System	04 Nov 2020 04:51:00

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:46', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8128710a-46d2-4974-a6e1-ca8d6a39ade1'	System	04 Nov 2020 04:51:00
User entered 'No (N)'	System	04 Nov 2020 04:51:00

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:49', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8128710a-46d2-4974-a6e1-ca8d6a39ade1'	System	04 Nov 2020 04:51:00
User entered 'No (N)'	System	04 Nov 2020 04:51:00

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:52', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8128710a-46d2-4974-a6e1-ca8d6a39ade1'	System	04 Nov 2020 04:51:00
User entered 'None (1)'	System	04 Nov 2020 04:51:00

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:54', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8128710a-46d2-4974-a6e1-ca8d6a39ade1'	System	04 Nov 2020 04:51:00
User entered '03 Nov 2020 21:53'	System	04 Nov 2020 04:51:00

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 7'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:34', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a6d4596a-658e-4b48-a895-cbf4f4207511'	System	05 Nov 2020 05:14:54
User entered 'None (1)'	System	05 Nov 2020 05:14:54

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:33', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a6d4596a-658e-4b48-a895-cbf4f4207511'	System	05 Nov 2020 05:14:54
User entered 'No (N)'	System	05 Nov 2020 05:14:54

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:37', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a6d4596a-658e-4b48-a895-cbf4f4207511'	System	05 Nov 2020 05:14:54
User entered 'No (N)'	System	05 Nov 2020 05:14:54

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:43', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a6d4596a-658e-4b48-a895-cbf4f4207511'	System	05 Nov 2020 05:14:54
User entered 'None (1)'	System	05 Nov 2020 05:14:54

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:49', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a6d4596a-658e-4b48-a895-cbf4f4207511'	System	05 Nov 2020 05:14:54
User entered '04 Nov 2020 22:17'	System	05 Nov 2020 05:14:54

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:46', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e8a3bdfc-dee9-4fd1-9033-f660c8a31f61'	System	29 Oct 2020 18:29:21
User entered 'None (0)'	System	29 Oct 2020 18:29:21

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:51', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e8a3bdfc-dee9-4fd1-9033-f660c8a31f61'	System	29 Oct 2020 18:29:21
User entered 'None (0)'	System	29 Oct 2020 18:29:21

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:31:54', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e8a3bdfc-dee9-4fd1-9033-f660c8a31f61'	System	29 Oct 2020 18:29:21
User entered 'None (0)'	System	29 Oct 2020 18:29:21

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:32:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e8a3bdfc-dee9-4fd1-9033-f660c8a31f61'	System	29 Oct 2020 18:29:21
User entered 'None (0)'	System	29 Oct 2020 18:29:21

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:32:02', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e8a3bdfc-dee9-4fd1-9033-f660c8a31f61'	System	29 Oct 2020 18:29:21
User entered 'None (0)'	System	29 Oct 2020 18:29:21

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:32:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e8a3bdfc-dee9-4fd1-9033-f660c8a31f61'	System	29 Oct 2020 18:29:21
User entered 'None (0)'	System	29 Oct 2020 18:29:21

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:32:14', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e8a3bdfc-dee9-4fd1-9033-f660c8a31f61'	System	29 Oct 2020 18:29:21
User entered 'No (N)'	System	29 Oct 2020 18:29:21

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T11:32:17', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e8a3bdfc-dee9-4fd1-9033-f660c8a31f61'	System	29 Oct 2020 18:29:21
User entered '29 Oct 2020 11:32'	System	29 Oct 2020 18:29:21

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 11:15'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 13:45'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:11', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ef8b574a-ae7a-4602-9e70-a347c0792107'	System	30 Oct 2020 02:19:34
User entered 'None (0)'	System	30 Oct 2020 02:19:34

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:13', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ef8b574a-ae7a-4602-9e70-a347c0792107'	System	30 Oct 2020 02:19:34
User entered 'None (0)'	System	30 Oct 2020 02:19:34

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:14', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ef8b574a-ae7a-4602-9e70-a347c0792107'	System	30 Oct 2020 02:19:34
User entered 'None (0)'	System	30 Oct 2020 02:19:34

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:17', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ef8b574a-ae7a-4602-9e70-a347c0792107'	System	30 Oct 2020 02:19:34
User entered 'None (0)'	System	30 Oct 2020 02:19:34

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:18', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ef8b574a-ae7a-4602-9e70-a347c0792107'	System	30 Oct 2020 02:19:34
User entered 'None (0)'	System	30 Oct 2020 02:19:34

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:20', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ef8b574a-ae7a-4602-9e70-a347c0792107'	System	30 Oct 2020 02:19:34
User entered 'None (0)'	System	30 Oct 2020 02:19:34

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:26', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ef8b574a-ae7a-4602-9e70-a347c0792107'	System	30 Oct 2020 02:19:34
User entered 'No (N)'	System	30 Oct 2020 02:19:34

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-29T19:22:29', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ef8b574a-ae7a-4602-9e70-a347c0792107'	System	30 Oct 2020 02:19:34
User entered '29 Oct 2020 19:22'	System	30 Oct 2020 02:19:34

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '29 Oct 2020 14:40'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 2'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:31', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '393c3a61-9883-4cf2-82a8-ea1ac151dbc8'	System	31 Oct 2020 02:09:59
User entered 'None (0)'	System	31 Oct 2020 02:09:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:34', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '393c3a61-9883-4cf2-82a8-ea1ac151dbc8'	System	31 Oct 2020 02:09:59
User entered 'No interference with activity (1)'	System	31 Oct 2020 02:09:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:37', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '393c3a61-9883-4cf2-82a8-ea1ac151dbc8'	System	31 Oct 2020 02:09:59
User entered 'No interference with activity (1)'	System	31 Oct 2020 02:09:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:43', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '393c3a61-9883-4cf2-82a8-ea1ac151dbc8'	System	31 Oct 2020 02:09:59
User entered 'None (0)'	System	31 Oct 2020 02:09:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:45', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '393c3a61-9883-4cf2-82a8-ea1ac151dbc8'	System	31 Oct 2020 02:09:59
User entered 'None (0)'	System	31 Oct 2020 02:09:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '393c3a61-9883-4cf2-82a8-ea1ac151dbc8'	System	31 Oct 2020 02:09:59
User entered 'None (0)'	System	31 Oct 2020 02:09:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:52', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '393c3a61-9883-4cf2-82a8-ea1ac151dbc8'	System	31 Oct 2020 02:09:59
User entered 'No (N)'	System	31 Oct 2020 02:09:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-30T19:12:55', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '393c3a61-9883-4cf2-82a8-ea1ac151dbc8'	System	31 Oct 2020 02:09:59
User entered '30 Oct 2020 19:12'	System	31 Oct 2020 02:09:59

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 3'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:38', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3ec670cc-dcce-4ceb-b112-7625e691c8cf'	System	01 Nov 2020 02:09:01
User entered 'None (0)'	System	01 Nov 2020 02:09:01

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:42', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3ec670cc-dcce-4ceb-b112-7625e691c8cf'	System	01 Nov 2020 02:09:01
User entered 'None (0)'	System	01 Nov 2020 02:09:01

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:44', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3ec670cc-dcce-4ceb-b112-7625e691c8cf'	System	01 Nov 2020 02:09:01
User entered 'None (0)'	System	01 Nov 2020 02:09:01

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:46', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3ec670cc-dcce-4ceb-b112-7625e691c8cf'	System	01 Nov 2020 02:09:01
User entered 'None (0)'	System	01 Nov 2020 02:09:01

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:49', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3ec670cc-dcce-4ceb-b112-7625e691c8cf'	System	01 Nov 2020 02:09:01
User entered 'None (0)'	System	01 Nov 2020 02:09:01

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:51', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3ec670cc-dcce-4ceb-b112-7625e691c8cf'	System	01 Nov 2020 02:09:01
User entered 'None (0)'	System	01 Nov 2020 02:09:01

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:54', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3ec670cc-dcce-4ceb-b112-7625e691c8cf'	System	01 Nov 2020 02:09:01
User entered 'No (N)'	System	01 Nov 2020 02:09:01

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-10-31T19:11:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3ec670cc-dcce-4ceb-b112-7625e691c8cf'	System	01 Nov 2020 02:09:01
User entered '31 Oct 2020 19:11'	System	01 Nov 2020 02:09:01

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 4'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:09', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a5df98e4-aa7e-4b9f-9743-abfc65219e12'	System	02 Nov 2020 01:04:28
User entered 'None (0)'	System	02 Nov 2020 01:04:28

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:11', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a5df98e4-aa7e-4b9f-9743-abfc65219e12'	System	02 Nov 2020 01:04:28
User entered 'None (0)'	System	02 Nov 2020 01:04:28

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:13', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a5df98e4-aa7e-4b9f-9743-abfc65219e12'	System	02 Nov 2020 01:04:28
User entered 'None (0)'	System	02 Nov 2020 01:04:28

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:14', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a5df98e4-aa7e-4b9f-9743-abfc65219e12'	System	02 Nov 2020 01:04:28
User entered 'None (0)'	System	02 Nov 2020 01:04:28

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:16', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a5df98e4-aa7e-4b9f-9743-abfc65219e12'	System	02 Nov 2020 01:04:28
User entered 'None (0)'	System	02 Nov 2020 01:04:28

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:18', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a5df98e4-aa7e-4b9f-9743-abfc65219e12'	System	02 Nov 2020 01:04:28
User entered 'None (0)'	System	02 Nov 2020 01:04:28

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:22', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a5df98e4-aa7e-4b9f-9743-abfc65219e12'	System	02 Nov 2020 01:04:28
User entered 'No (N)'	System	02 Nov 2020 01:04:28

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-01T18:07:24', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a5df98e4-aa7e-4b9f-9743-abfc65219e12'	System	02 Nov 2020 01:04:28
User entered '01 Nov 2020 18:07'	System	02 Nov 2020 01:04:28

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 5'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:11', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6e0d9d80-37e2-4f4b-8534-28239bd30865'	System	03 Nov 2020 00:50:41
User entered 'None (0)'	System	03 Nov 2020 00:50:41

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:13', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6e0d9d80-37e2-4f4b-8534-28239bd30865'	System	03 Nov 2020 00:50:41
User entered 'None (0)'	System	03 Nov 2020 00:50:41

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6e0d9d80-37e2-4f4b-8534-28239bd30865'	System	03 Nov 2020 00:50:41
User entered 'No interference with activity (1)'	System	03 Nov 2020 00:50:41

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:27', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6e0d9d80-37e2-4f4b-8534-28239bd30865'	System	03 Nov 2020 00:50:41
User entered 'None (0)'	System	03 Nov 2020 00:50:41

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:29', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6e0d9d80-37e2-4f4b-8534-28239bd30865'	System	03 Nov 2020 00:50:41
User entered 'None (0)'	System	03 Nov 2020 00:50:41

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:31', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6e0d9d80-37e2-4f4b-8534-28239bd30865'	System	03 Nov 2020 00:50:41
User entered 'None (0)'	System	03 Nov 2020 00:50:41

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:34', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6e0d9d80-37e2-4f4b-8534-28239bd30865'	System	03 Nov 2020 00:50:41
User entered 'No (N)'	System	03 Nov 2020 00:50:41

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-02T17:53:37', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6e0d9d80-37e2-4f4b-8534-28239bd30865'	System	03 Nov 2020 00:50:41
User entered '02 Nov 2020 17:53'	System	03 Nov 2020 00:50:41

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 6'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:53:58', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ec58b90e-ec58-477d-932f-f088671c3d73'	System	04 Nov 2020 04:51:37
User entered 'None (0)'	System	04 Nov 2020 04:51:37

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:54:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ec58b90e-ec58-477d-932f-f088671c3d73'	System	04 Nov 2020 04:51:37
User entered 'None (0)'	System	04 Nov 2020 04:51:37

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:54:02', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ec58b90e-ec58-477d-932f-f088671c3d73'	System	04 Nov 2020 04:51:37
User entered 'None (0)'	System	04 Nov 2020 04:51:37

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:54:03', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ec58b90e-ec58-477d-932f-f088671c3d73'	System	04 Nov 2020 04:51:37
User entered 'None (0)'	System	04 Nov 2020 04:51:37

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:54:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ec58b90e-ec58-477d-932f-f088671c3d73'	System	04 Nov 2020 04:51:37
User entered 'None (0)'	System	04 Nov 2020 04:51:37

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:54:07', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ec58b90e-ec58-477d-932f-f088671c3d73'	System	04 Nov 2020 04:51:37
User entered 'None (0)'	System	04 Nov 2020 04:51:37

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:54:29', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ec58b90e-ec58-477d-932f-f088671c3d73'	System	04 Nov 2020 04:51:37
User entered 'No (N)'	System	04 Nov 2020 04:51:37

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-03T21:54:32', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'ec58b90e-ec58-477d-932f-f088671c3d73'	System	04 Nov 2020 04:51:37
User entered '03 Nov 2020 21:54'	System	04 Nov 2020 04:51:37

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
Data entry locked.	System	29 Oct 2020 18:03:23
User entered 'Day 7'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:53', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2d79e4d6-5475-4f5f-b70a-e24d6f026633'	System	05 Nov 2020 05:15:17
User entered 'None (0)'	System	05 Nov 2020 05:15:17

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:55', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2d79e4d6-5475-4f5f-b70a-e24d6f026633'	System	05 Nov 2020 05:15:17
User entered 'None (0)'	System	05 Nov 2020 05:15:17

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2d79e4d6-5475-4f5f-b70a-e24d6f026633'	System	05 Nov 2020 05:15:17
User entered 'None (0)'	System	05 Nov 2020 05:15:17

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:17:59', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2d79e4d6-5475-4f5f-b70a-e24d6f026633'	System	05 Nov 2020 05:15:17
User entered 'None (0)'	System	05 Nov 2020 05:15:17

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:18:01', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2d79e4d6-5475-4f5f-b70a-e24d6f026633'	System	05 Nov 2020 05:15:17
User entered 'None (0)'	System	05 Nov 2020 05:15:17

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:18:03', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2d79e4d6-5475-4f5f-b70a-e24d6f026633'	System	05 Nov 2020 05:15:17
User entered 'None (0)'	System	05 Nov 2020 05:15:17

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:18:06', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2d79e4d6-5475-4f5f-b70a-e24d6f026633'	System	05 Nov 2020 05:15:17
User entered 'No (N)'	System	05 Nov 2020 05:15:17

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-04T22:18:12', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2d79e4d6-5475-4f5f-b70a-e24d6f026633'	System	05 Nov 2020 05:15:17
User entered '04 Nov 2020 22:18'	System	05 Nov 2020 05:15:17

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 18:03:23

US3562205

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:36:59
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 18:03:23

US3562205

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:53:25

US3562205

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '5 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:53:25

US3562205

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:53:25

US3562205

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:53:25

US3562205

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:53:29

US3562205

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'l'	System	05 Nov 2020 22:53:29

US3562205

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 20:52:20

US3562205

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '12 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 20:52:20

US3562205

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 20:52:20

US3562205

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 20:52:20

US3562205

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 20:52:24

US3562205

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'l'	System	12 Nov 2020 20:52:24

US3562205

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 19:19:48

US3562205

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '19 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 19:19:48

US3562205

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 19:19:48

US3562205

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 19:19:48

US3562205

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 19:19:54

US3562205

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'l'	System	19 Nov 2020 19:19:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:28

US3562205

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '25 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:28

US3562205

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:28

US3562205

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'VISIT3'	System	25 Nov 2020 19:17:28

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '25 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '09:31'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '25 Nov 2020 09:31'	System	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '97.8' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '77'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'bpm'	System	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '14'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'breaths/min'	System	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '135'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '70'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'mmHg'	System	25 Nov 2020 19:17:54

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43

US3562205

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43

US3562205

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:59

US3562205

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '25 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:17:59

US3562205

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:18:11

US3562205

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '25 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:18:11

US3562205

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered '09:40'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:18:11

US3562205

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered '25 Nov 2020 09:40'	System	25 Nov 2020 19:18:11

US3562205

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:02:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Nov 2020 19:19:07

US3562205

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'I'	System	25 Nov 2020 19:19:07

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2020-11-28T17:49:39', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8bf887d1-a124-4d37-a107-62406dabeeb1'	System	29 Nov 2020 00:46:58
User entered 'No (N)'	System	29 Nov 2020 00:46:58

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2020-11-28T17:49:55', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8bf887d1-a124-4d37-a107-62406dabeeb1'	System	29 Nov 2020 00:46:58
User entered 'No (N)'	System	29 Nov 2020 00:46:58

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-11-28T17:50:14', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8bf887d1-a124-4d37-a107-62406dabeeb1'	System	29 Nov 2020 00:46:58
User entered '28 Nov 2020 17:50:14'	System	29 Nov 2020 00:46:58

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2020-12-05T12:28:58', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '411debbdf-2a3e-482c-9b38-e7919d83c716'	System	05 Dec 2020 19:25:40
User entered 'No (N)'	System	05 Dec 2020 19:25:40

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2020-12-05T12:28:50', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '411debbdf-2a3e-482c-9b38-e7919d83c716'	System	05 Dec 2020 19:25:40
User entered 'No (N)'	System	05 Dec 2020 19:25:40

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-12-05T12:29:05', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '411debbdf-2a3e-482c-9b38-e7919d83c716'	System	05 Dec 2020 19:25:40
User entered '05 Dec 2020 12:29:05'	System	05 Dec 2020 19:25:40

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2020-12-12T12:30:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '65cf2903-0d2a-4716-9411-117255e01f17'	System	12 Dec 2020 19:27:36
User entered 'No (N)'	System	12 Dec 2020 19:27:36

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2020-12-12T12:30:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '65cf2903-0d2a-4716-9411-117255e01f17'	System	12 Dec 2020 19:27:36
User entered 'No (N)'	System	12 Dec 2020 19:27:36

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-12-12T12:31:03', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '65cf2903-0d2a-4716-9411-117255e01f17'	System	12 Dec 2020 19:27:36
User entered '12 Dec 2020 12:31:03'	System	12 Dec 2020 19:27:36

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2020-12-21T08:31:09', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3c456bff-bd78-43ae-9ac9-7479551cc0cd'	System	21 Dec 2020 15:27:55
User entered 'No (N)'	System	21 Dec 2020 15:27:55

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2020-12-21T08:31:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3c456bff-bd78-43ae-9ac9-7479551cc0cd'	System	21 Dec 2020 15:27:55
User entered 'No (N)'	System	21 Dec 2020 15:27:55

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-12-21T08:31:27', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '3c456bff-bd78-43ae-9ac9-7479551cc0cd' User entered '21 Dec 2020 08:31:27'	System	21 Dec 2020 15:27:55
	System	21 Dec 2020 15:27:55

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2020-12-26T00:01:49', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '895067a4-e38c-4e17-9847-414fdb2352ff'	System	26 Dec 2020 06:58:30
User entered 'No (N)'	System	26 Dec 2020 06:58:30

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2020-12-26T00:01:57', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '895067a4-e38c-4e17-9847-414fdb2352ff'	System	26 Dec 2020 06:58:30
User entered 'No (N)'	System	26 Dec 2020 06:58:30

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2020-12-26T00:02:03', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '895067a4-e38c-4e17-9847-414fdb2352ff'	System	26 Dec 2020 06:58:30
User entered '26 Dec 2020 00:02:03'	System	26 Dec 2020 06:58:30

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2021-01-02T11:42:35', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '316205fb-af14-4c9e-8bd2-b76d63c240e2'	System	02 Jan 2021 18:38:56
User entered 'No (N)'	System	02 Jan 2021 18:38:56

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2021-01-02T11:42:41', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '316205fb-af14-4c9e-8bd2-b76d63c240e2'	System	02 Jan 2021 18:38:56
User entered 'No (N)'	System	02 Jan 2021 18:38:56

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2021-01-02T11:42:45', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '316205fb-af14-4c9e-8bd2-b76d63c240e2'	System	02 Jan 2021 18:38:56
User entered '02 Jan 2021 11:42:45'	System	02 Jan 2021 18:38:56

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2021-01-09T10:00:02', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8a0d1a75-d62a-41ad-b217-e272a3090b32'	System	09 Jan 2021 16:56:15
User entered 'No (N)'	System	09 Jan 2021 16:56:15

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2021-01-09T10:00:07', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8a0d1a75-d62a-41ad-b217-e272a3090b32'	System	09 Jan 2021 16:56:15
User entered 'No (N)'	System	09 Jan 2021 16:56:15

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2021-01-09T10:00:11', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '8a0d1a75-d62a-41ad-b217-e272a3090b32'	System	09 Jan 2021 16:56:15
User entered '09 Jan 2021 10:00:11'	System	09 Jan 2021 16:56:15

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2021-01-16T09:49:23', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e212165a-cd2d-4a45-bb33-880106c515e8'	System	16 Jan 2021 16:45:29
User entered 'No (N)'	System	16 Jan 2021 16:45:29

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2021-01-16T09:49:26', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e212165a-cd2d-4a45-bb33-880106c515e8'	System	16 Jan 2021 16:45:29
User entered 'No (N)'	System	16 Jan 2021 16:45:29

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2021-01-16T09:49:34', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'e212165a-cd2d-4a45-bb33-880106c515e8'	System	16 Jan 2021 16:45:29
User entered '16 Jan 2021 09:49:34'	System	16 Jan 2021 16:45:29

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (f1f095b6cf928cf3)', Time: '2021-01-24T19:58:20', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6154841a-cc15-4c62-bcc8-0a1ed1536ad4'	System	25 Jan 2021 02:54:32
User entered 'Yes (Y)'	System	25 Jan 2021 02:54:32

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (f1f095b6cf928cf3)', Time: '2021-01-24T19:58:26', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6154841a-cc15-4c62-bcc8-0a1ed1536ad4'	System	25 Jan 2021 02:54:32
User entered 'No (N)'	System	25 Jan 2021 02:54:32

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2021-01-24T19:58:31', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6154841a-cc15-4c62-bcc8-0a1ed1536ad4'	System	25 Jan 2021 02:54:32
User entered 'No (N)'	System	25 Jan 2021 02:54:32

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2021-01-24T19:58:37', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6154841a-cc15-4c62-bcc8-0a1ed1536ad4'	System	25 Jan 2021 02:54:32
User entered 'Yes (Y)'	System	25 Jan 2021 02:54:32

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2021-01-24T19:58:43', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6154841a-cc15-4c62-bcc8-0a1ed1536ad4'	System	25 Jan 2021 02:54:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 02:54:32

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1f095b6cf928cf3)', Time: '2021-01-24T19:58:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '6154841a-cc15-4c62-bcc8-0a1ed1536ad4'	System	25 Jan 2021 02:54:32
User entered '24 Jan 2021 19:58:48'	System	25 Jan 2021 02:54:32

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-01-30T12:30:54', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2c7bedcd-bab1-4f8e-bd7c-7086dd7d0cd9'	System	30 Jan 2021 19:31:07
User entered 'No (N)'	System	30 Jan 2021 19:31:07

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-01-30T12:30:59', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2c7bedcd-bab1-4f8e-bd7c-7086dd7d0cd9'	System	30 Jan 2021 19:31:07
User entered 'No (N)'	System	30 Jan 2021 19:31:07

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-01-30T12:31:02', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2c7bedcd-bab1-4f8e-bd7c-7086dd7d0cd9' User entered '30 Jan 2021 12:31:02'	System	30 Jan 2021 19:31:07
	System	30 Jan 2021 19:31:07

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-02-06T07:48:07', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a2397d65-f464-4d3a-9da7-398cf9b7416f' User entered 'No (N)'	System	06 Feb 2021 14:48:24

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-02-06T07:48:13', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a2397d65-f464-4d3a-9da7-398cf9b7416f'	System	06 Feb 2021 14:48:24
User entered 'No (N)'	System	06 Feb 2021 14:48:24

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-02-06T07:48:20', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a2397d65-f464-4d3a-9da7-398cf9b7416f' User entered '06 Feb 2021 07:48:20'	System	06 Feb 2021 14:48:24

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-02-13T09:11:47', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '34b8f8d3-6a85-4760-83a8-565049ec818c'	System	13 Feb 2021 16:11:59
User entered 'No (N)'	System	13 Feb 2021 16:11:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-02-13T09:11:51', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '34b8f8d3-6a85-4760-83a8-565049ec818c'	System	13 Feb 2021 16:11:59
User entered 'No (N)'	System	13 Feb 2021 16:11:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-02-13T09:11:55', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '34b8f8d3-6a85-4760-83a8-565049ec818c'	System	13 Feb 2021 16:11:59
User entered '13 Feb 2021 09:11:55'	System	13 Feb 2021 16:11:59

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-02-20T12:43:41', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1e0af606-9172-4cfd-af95-af968029e8c6'	System	20 Feb 2021 19:43:54
User entered 'No (N)'	System	20 Feb 2021 19:43:54

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-02-20T12:43:44', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1e0af606-9172-4cfd-af95-af968029e8c6'	System	20 Feb 2021 19:43:54
User entered 'No (N)'	System	20 Feb 2021 19:43:54

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-02-20T12:43:48', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1e0af606-9172-4cfd-af95-af968029e8c6'	System	20 Feb 2021 19:43:54
User entered '20 Feb 2021 12:43:48'	System	20 Feb 2021 19:43:54

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-02-27T12:37:06-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd12f25c4-66d1-497f-81e9-656509ad6e32'	System	27 Feb 2021 19:37:16
User entered 'No (N)'	System	27 Feb 2021 19:37:16

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-02-27T12:37:09-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd12f25c4-66d1-497f-81e9-656509ad6e32'	System	27 Feb 2021 19:37:16
User entered 'No (N)'	System	27 Feb 2021 19:37:16

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-02-27T12:37:13-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'd12f25c4-66d1-497f-81e9-656509ad6e32'	System	27 Feb 2021 19:37:16
User entered '27 Feb 2021 12:37:13'	System	27 Feb 2021 19:37:16

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-03-06T11:01:23-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2689d035-f6a5-4ad4-bbd0-1edfbe7bfc6f' User entered 'No (N)'	System	06 Mar 2021 18:02:56
	System	06 Mar 2021 18:02:56

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-03-06T11:01:26-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2689d035-f6a5-4ad4-bbd0-1edfbe7bfc6f' User entered 'No (N)'	System	06 Mar 2021 18:02:56

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-03-06T11:01:32-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '2689d035-f6a5-4ad4-bbd0-1edfbe7bfc6f' User entered '06 Mar 2021 11:01:32'	System	06 Mar 2021 18:02:56
	System	06 Mar 2021 18:02:56

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-03-13T12:39:50-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'aa4a84a6-26b2-4259-8ee2-65a83d916a0d' User entered 'No (N)'	System	13 Mar 2021 19:40:15
	System	13 Mar 2021 19:40:15

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-03-13T12:40:06-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'aa4a84a6-26b2-4259-8ee2-65a83d916a0d'	System	13 Mar 2021 19:40:15
User entered 'No (N)'	System	13 Mar 2021 19:40:15

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-03-13T12:40:10-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'aa4a84a6-26b2-4259-8ee2-65a83d916a0d' User entered '13 Mar 2021 12:40:10'	System	13 Mar 2021 19:40:15
	System	13 Mar 2021 19:40:15

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-03-20T12:32:01-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '392d40c4-7c01-4ec6-bb25-904a4167337d' User entered 'Yes (Y)'	System	20 Mar 2021 19:32:50
	System	20 Mar 2021 19:32:50

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-03-20T12:32:04-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '392d40c4-7c01-4ec6-bb25-904a4167337d'	System	20 Mar 2021 19:32:50
User entered 'No (N)'	System	20 Mar 2021 19:32:50

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-03-20T12:32:12-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '392d40c4-7c01-4ec6-bb25-904a4167337d'	System	20 Mar 2021 19:32:50
User entered 'No (N)'	System	20 Mar 2021 19:32:50

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-03-20T12:32:28-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '392d40c4-7c01-4ec6-bb25-904a4167337d' User entered 'Yes (Y)'	System	20 Mar 2021 19:32:50
	System	20 Mar 2021 19:32:50

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-03-20T12:32:35-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '392d40c4-7c01-4ec6-bb25-904a4167337d'	System	20 Mar 2021 19:32:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Mar 2021 19:32:50

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-03-20T12:32:40-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '392d40c4-7c01-4ec6-bb25-904a4167337d' User entered '20 Mar 2021 12:32:40'	System	20 Mar 2021 19:32:50
	System	20 Mar 2021 19:32:50

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-03-27T09:33:50-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1bde16e0-e5c6-4257-8793-7340c6acddd3' User entered 'No (N)'	System	27 Mar 2021 16:34:04

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-03-27T09:33:53-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1bde16e0-e5c6-4257-8793-7340c6acddd3'	System	27 Mar 2021 16:34:04
User entered 'No (N)'	System	27 Mar 2021 16:34:04

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-03-27T09:33:58-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '1bde16e0-e5c6-4257-8793-7340c6acddd3' User entered '27 Mar 2021 09:33:58'	System	27 Mar 2021 16:34:04
	System	27 Mar 2021 16:34:04

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-04-03T11:00:39-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '64d25f61-7cab-4639-b004-0d1d83c1f084'	System	03 Apr 2021 18:00:53
User entered 'No (N)'	System	03 Apr 2021 18:00:53

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-04-03T11:00:45-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '64d25f61-7cab-4639-b004-0d1d83c1f084'	System	03 Apr 2021 18:00:53
User entered 'No (N)'	System	03 Apr 2021 18:00:53

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-04-03T11:00:49-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '64d25f61-7cab-4639-b004-0d1d83c1f084'	System	03 Apr 2021 18:00:53
User entered '03 Apr 2021 11:00:49'	System	03 Apr 2021 18:00:53

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-04-10T00:59:39-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a3b3f626-2436-46de-b7e8-e2437de4d8e8'	System	10 Apr 2021 07:59:49
User entered 'No (N)'	System	10 Apr 2021 07:59:49

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-04-10T00:59:42-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a3b3f626-2436-46de-b7e8-e2437de4d8e8'	System	10 Apr 2021 07:59:49
User entered 'No (N)'	System	10 Apr 2021 07:59:49

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-04-10T00:59:46-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'a3b3f626-2436-46de-b7e8-e2437de4d8e8'	System	10 Apr 2021 07:59:49
User entered '10 Apr 2021 00:59:46'	System	10 Apr 2021 07:59:49

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-04-17T12:31:51-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'cfd34818-2436-460c-a778-038dc338e4b1' User entered 'No (N)'	System	17 Apr 2021 19:32:05
	System	17 Apr 2021 19:32:05

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-04-17T12:31:55-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'cfd34818-2436-460c-a778-038dc338e4b1'	System	17 Apr 2021 19:32:05
User entered 'No (N)'	System	17 Apr 2021 19:32:05

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-04-17T12:31:58-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'cfd34818-2436-460c-a778-038dc338e4b1'	System	17 Apr 2021 19:32:05
User entered '17 Apr 2021 12:31:58'	System	17 Apr 2021 19:32:05

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-04-24T08:29:33-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '64419f0b-6dd6-4ba6-83a6-7f4ac122726d' User entered 'No (N)'	System	24 Apr 2021 15:29:49
	System	24 Apr 2021 15:29:49

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-04-24T08:29:39-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '64419f0b-6dd6-4ba6-83a6-7f4ac122726d' User entered 'No (N)'	System	24 Apr 2021 15:29:49

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-04-24T08:29:44-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '64419f0b-6dd6-4ba6-83a6-7f4ac122726d' User entered '24 Apr 2021 08:29:44'	System	24 Apr 2021 15:29:49
	System	24 Apr 2021 15:29:49

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[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 (3c2c26d3a4c582bb)', Time: '2021-05-01T08:31:52-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c12da5bd-ae7c-4889-bb2f-f9a1e9241e23'	System	01 May 2021 15:32:07
User entered 'No (N)'	System	01 May 2021 15:32:07

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Have you been exposed to someone with 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 (3c2c26d3a4c582bb)', Time: '2021-05-01T08:31:55-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c12da5bd-ae7c-4889-bb2f-f9a1e9241e23'	System	01 May 2021 15:32:07
User entered 'No (N)'	System	01 May 2021 15:32:07

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-05-01T08:32:00-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: 'c12da5bd-ae7c-4889-bb2f-f9a1e9241e23'	System	01 May 2021 15:32:07
User entered '01 May 2021 08:32:00'	System	01 May 2021 15:32:07

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 11:28:23

US3562205

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:28:23
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 11:28:23

US3562205

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:13:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:59:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-02-27T12:37:21-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '536c977d-1504-4d6c-8933-47ca67d691e9'	System	27 Feb 2021 19:37:34
User entered 'No (N)'	System	27 Feb 2021 19:37:34

US3562205

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:13:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:59:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c2c26d3a4c582bb)', Time: '2021-02-27T12:37:29-07:00', User OID: 'PatientReportedOutcome (US3562205)', ODM File OID: '536c977d-1504-4d6c-8933-47ca67d691e9' User entered '27 Feb 2021 12:37:29'	System	27 Feb 2021 19:37:34
	System	27 Feb 2021 19:37:34

US3562205

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Dec 2020 17:52:35

US3562205

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered '21 Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Dec 2020 17:52:35

US3562205

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Dec 2020 17:52:35

US3562205

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Dec 2020 17:52:35

US3562205

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:42:18
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Dec 2020 17:52:41

US3562205

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:27:43
User entered 'l'	System	22 Dec 2020 17:52:41

US3562205

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:03:14

US3562205

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:03:14

US3562205

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:03:14

US3562205

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:03:14

US3562205

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:03:20

US3562205

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User entered 'l'	System	08 Feb 2021 17:03:20

US3562205

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Feb 2021 19:02:01

US3562205

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered '26 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Feb 2021 19:02:01

US3562205

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Feb 2021 19:02:01

US3562205

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Feb 2021 19:02:01

US3562205

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:35:01
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Feb 2021 19:02:08

US3562205

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User entered 'l'	System	26 Feb 2021 19:02:08

US3562205

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:07
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:54:29

US3562205

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:07
User entered '29 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:54:29

US3562205

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:54:29

US3562205

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:07
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:54:29

US3562205

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:07
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:54:35

US3562205

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:40:57
User entered 'l'	System	29 Mar 2021 20:54:35

US3562205

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4)	16 Apr 2021 16:38:50

US3562205

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:38:50

US3562205

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:38:50

US3562205

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	16 Apr 2021 16:38:50

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '09:24'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
User entered '16 Apr 2021 09:24'	System	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '98.0' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '60'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '18'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '118'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '81'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 16:39:33

US3562205

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:38:55

US3562205

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:38:55

US3562205

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:13

US3562205

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:39:13

US3562205

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered '09:31'	(b) (4) Dhwani Shah (b) (4)	16 Apr 2021 16:39:13
	(b) (4)	

US3562205

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Apr 2021 09:31'	System	16 Apr 2021 16:39:13

US3562205

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Apr 2021 16:38:59

US3562205

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	16 Apr 2021 16:38:59

US3562205

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:03

US3562205

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered '25 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:03

US3562205

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:03

US3562205

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 23:00:03

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered '25 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:23

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:21:11

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:23

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:21:11

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered '25 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:23

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:23

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:23

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:23

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:23

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	25 Jan 2021 23:00:23

US3562205

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered empty.	System	25 Jan 2021 23:00:23

US3562205

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:42

US3562205

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered '25 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:42

US3562205

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered '08:32'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:42

US3562205

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '25 Jan 2021 08:32'	System	25 Jan 2021 23:00:42

US3562205

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:51

US3562205

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered '25 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:51

US3562205

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:46:09
User entered '08:35'	(b) (4) Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 23:00:51

US3562205

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:36

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:32:47
User entered '25 Jan 2021 08:35'	System	25 Jan 2021 23:00:51

US3562205

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:13:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:03:54
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:54:28
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:00:22
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:00:02

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:31:47
Reviewed for Safety.		26 Jan 2021 17:56:29
User entered	System	26 Jan 2021 17:56:24
'USA-US071-2021-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	26 Jan 2021 17:56:24

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:31:49
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis aggravated - version MedDRA\23.0.	Coder Import (b) (4)	25 Jan 2021 22:58:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Jan 2021 22:58:01
Data point term sent to Coder	System	25 Jan 2021 22:57:27
User entered 'WORSENING OF DIVERTICULITIS'	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18
	(b) (4)	

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:31:51
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18
	(b) (4)	

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:31:57
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:05
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:09
User closed 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).	System	25 Jan 2021 22:57:37
User closed query 'The Start Date for Adverse Event 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	25 Jan 2021 22:57:37
User entered '20 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:37
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).	System	25 Jan 2021 22:57:18
User opened query 'The Start Date for Adverse Event 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	25 Jan 2021 22:57:18
User entered '20 Jan 2020'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:11
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:23
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Jan 2021 22:58:04
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:58:04
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Jan 2021 22:57:18
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:32:32
User closed query 'PV Query: Please confirm end date of 04 Feb 2021 as discharge date is 24 Jan 2021. Was subject still having symptoms or experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:11:55
Query 'PV Query: Please confirm end date of 04 Feb 2021 as discharge date is 24 Jan 2021. Was subject still having symptoms or experience another SAE?' answered with 'confirmed end date is 04feb2021. pt was on medication # 8-9 for worsenign diverticulitis ' (Site from Safety).	Dhwani Shah (b) (4)	19 Feb 2021 22:48:53
User opened query 'PV Query: Please confirm end date of 04 Feb 2021 as discharge date is 24 Jan 2021. Was subject still having symptoms or experience another SAE?' (Site from Safety).	(b) (4)	
User entered '04 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 14:04:41
User entered '24 Jan 2021'	Dhwani Shah (b) (4)	08 Feb 2021 17:41:11
	(b) (4)	
	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18
	(b) (4)	

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:34
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:36
User entered 'Grade 4 (Grade 4)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:32:38
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Jan 2021 22:58:04
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Jan 2021 22:57:18
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:41
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:32:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:32:45
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		25 Jan 2021 22:58:04
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		25 Jan 2021 22:58:04
User entered '1' reason for change: Data Entry Error	Dhwani Shah (b) (4)	25 Jan 2021 22:58:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	25 Jan 2021 22:57:18
User entered '0'	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18
	(b) (4)	

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:28:47
User entered '21 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:41:11
User entered '20 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:11:01
User entered '21 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:49
User entered '24 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4)	08 Feb 2021 17:41:11
User entered '04 Feb 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4)	08 Feb 2021 17:10:10
User entered '24 Jan 2021'	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:05
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:07
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:10
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:34:11
User entered '0'	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:17
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:34:19
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18
	(b) (4)	

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:23
User entered 'Not Applicable (NOT APPLICABLE)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:26
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:34:28
User entered 'l'	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:30
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:34:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Narrative = MICROPERFORATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:09:42
User closed query 'Per DM CLR: Narrative = FLU A/B, RSV RAPID PANEL DONE ON 1/22/21. 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)	12 Mar 2021 07:38:55
Query 'Per DM CLR: Narrative = MICROPERFORATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'MICROPERFORMATION IS NOT A DIAGNOSIS AND NO SEPRATE AE NEED TO CREATE ' (Site from DM).	Dhwani Shah (b) (4)	11 Mar 2021 16:00:24
Query 'Per DM CLR: Narrative = FLU A/B, RSV RAPID PANEL DONE ON 1/22/21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'this is lab test not a procedure and did not capture under conprocedure eCRF' (Site from DM).	Dhwani Shah (b) (4)	10 Mar 2021 22:50:54
User opened query 'Per DM CLR: Narrative = MICROPERFORATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:52:49
User opened query 'Per DM CLR: Narrative = FLU A/B, RSV RAPID PANEL DONE ON 1/22/21. 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)	09 Mar 2021 06:52:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:35:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify CT scan vs Xray (or both) as history and physical in the medical records says CT showed acute sigmoid diverticulitis with microperforation.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:11:58
User entered 'DIVERTICULITIS DX OF 2013, NO EPISODE UNTILL JAN20TH 21 , WENT TO ER-XRAY DONE AND GOT ADMITTED TO HOSPITAL, DISCHARGE ON 24TH JAN 21, UPDATED CONMED XRAY ABDOMINAL FINDING THERE IS NON OBSRTUCTIVE BOWEL GAS PATTERN. THERE IS NO ABNORMAL DILATION OF BOWEL LOOPS. THERE IS NO PNEUMATOSIS OR MASS EFFECT . COMPLETED COVID 19 PUI,FLU A/B, RSV RAPID PANEL DONE ON 1/22/21 AND RESULTS ARE NEGATIVE FOR COVID 19, INFLUENZA A,B AND RSV, CT WAS DONE ON 1/21/21 SHOWED ACUTE SIGNMOID DIVERTICULITIS WITH MICROPERFORATION' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:55:55
Query 'PV Query: Please clarify CT scan vs Xray (or both) as history and physical in the medical records says CT showed acute sigmoid diverticulitis with microperforation.' answered with 'UPDATED NARRATIVE, BOTH CT SCAN AND XRAY ' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:53:46

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DIVERTICULITIS DX OF 2013, NO EPISODE UNTILL JAN20TH 21 , WENT TO ER-XRAY DONE AND GOT ADMITTED TO HOSPITAL, DISCHARGE ON 24TH JAN 21, UPDATED CONMED XRAY ABDOMINAL FINDING THERE IS NON OBSRTUCTIVE BOWEL GAS PATTERN. THERE IS NO ABNORMAL DILATION OF BOWEL LOOPS. THERE IS NO PNEUMATOSIS OR MASS EFFECT . COMPLETED COVID 19 PUI,FLU A/B, RSV RAPID PANEL DONE ON 1/22/21 AND RESULTS ARE NEGATIVE FOR COVID 19, INFLUENZA A,B AND RSV, CT WAS DONE ON 1/22/21 SHOWED ACUTE SIGNMOID DIVERTICULITIS WITH MICROPERFORATION'	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:53:23
reason for change: Data Entry Error User opened query 'PV Query: Please clarify CT scan vs Xray (or both) as history and physical in the medical records says CT showed acute sigmoid diveritculitis with microperforation.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:05:43
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:57:12
User closed query 'PV Query: Please provide the results of the CT scan. ' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:57:04
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'UPDATED NARRATIVE WITH ALL INFO ' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 15:44:59

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DIVERTICULITIS DX OF 2013, NO EPISODE UNTILL JAN20TH 21 , WENT TO ER-xray DONE AND GOT ADMITTED TO HOSPITAL, DISCHARGE ON 24TH JAN 21, UPDATED CONMED Xray abdominal finding there is non obsrtuctive bowel gas pattern. there is no abnormal dilation of bowel loops. there is no pneumatosis or mass effect . completed COVID 19 PUI,FLU A/B, RSV RAPID PANEL DONE ON 1/22/21 AND RESULTS ARE NEGATIVE FOR COVID 19, INFLUENZA A,B AND RSV' reason for change: Data Entry Error	Dhwani Shah (b) (4)	09 Feb 2021 15:44:28
Query 'PV Query: Please provide the results of the CT scan. ' answered with 'per medical records xray was done not CT scan. updated narrative with right info ' (Site from Safety).	Dhwani Shah (b) (4)	09 Feb 2021 15:42:02
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 13:23:17
User closed query 'PV 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 Safety).	(b) (4), (b) (6)	09 Feb 2021 13:23:16
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Fax medical records on 2/8/21 at 10:25am ' (Site from Safety).	Dhwani Shah (b) (4)	08 Feb 2021 17:33:09

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV 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 'updated conmeds' (Site from Safety).	Dhwani Shah (b) (4)	08 Feb 2021 17:20:32
User opened query 'PV Query: Please provide the results of the CT scan. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 15:14:32
User opened query 'PV 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 Safety).	(b) (4), (b) (6)	04 Feb 2021 15:14:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 15:13:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 15:13:11
User entered 'DIVERTICULITIS DX OF 2013, NO EPISODE UNTILL JAN20TH 21 , WENT TO ER-CT DONE AND GOT ADMITTED TO HOSPITAL, DISCHARGE ON 24TH JAN 21, UPDATED CONMED'	Dhwani Shah (b) (4)	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 22:57:18

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis aggravated - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Mar 2021 21:01:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 21:01:10
Data point term sent to Coder	System	29 Mar 2021 20:59:56
User entered 'WORSENING DIVERTICULITIS'	Dhwani Shah (b) (4)	29 Mar 2021 20:59:54
	(b) (4)	

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '19 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User entered empty.	System	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '26 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User entered empty.	System	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Mar 2021 20:59:59
User entered '0'	System	29 Mar 2021 20:59:54
	Dhwani Shah (b) (4)	29 Mar 2021 20:59:54
	(b) (4)	

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	29 Mar 2021 20:59:59
User entered '0'	(b) (4)	
	Dhwani Shah (b) (4)	29 Mar 2021 20:59:54
	(b) (4)	

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User entered '0'	System	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20
User entered 'I'	System	29 Mar 2021 20:59:54

US3562205

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:13:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:57:20

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:13:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:03:54
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:38:05
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:00:38

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Oct 2020 16:01:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 16:01:42
Data point term sent to Coder	System	03 Oct 2020 16:01:15
User entered 'Zyrtec'	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please update the indication to reflect the type of SEASONAL ALLERGIES. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 00:09:04
Query 'Per DM CLR: Please update the indication to reflect the type of SEASONAL ALLERGIES. Review and update indication and ensure to update MH eCRF as appropriate. ' answered with 'unknown ! confirmed as it is' (Site from DM).	Dhwani Shah (b) (4)	24 Nov 2020 20:06:22
User opened query 'Per DM CLR: Please update the indication to reflect the type of SEASONAL ALLERGIES. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:05:15
User entered 'seasonal allergies'	Dhwani Shah (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:27:10
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'unknown! confirmed as it is ' (Site from DM).	Dhwani Shah (b) (4)	24 Nov 2020 20:06:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:04:58
User entered 'I'	Dhwani Shah (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'tablet (TABLET)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un UNK 2018'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 16:01:10

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 22:37:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:37:28
Data point term sent to Coder	System	14 Oct 2020 22:13:57
User entered 'naproxen'	Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 10:31:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	04 Dec 2020 16:56:29
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:09:23

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User entered 'headache caffeine withdrawal'	Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'confirmed as it is per pt ' (Site from DM). User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User entered '200'	(b) (4), (b) (6) Dhwani Shah (b) (4) (b) (4) (b) (4), (b) (6) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 03:30:24 09 Feb 2021 20:49:43 28 Jan 2021 05:36:24 14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'as needed (PRN)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
	(b) (4)	
User entered 'un UNK 2017' reason for change: Data Entry Error	Dhwani Shah (b) (4)	04 Dec 2020 16:56:22
	(b) (4)	
User entered '03 Oct 2020'	Dhwani Shah (b) (4)	14 Oct 2020 22:12:57
	(b) (4)	

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 22:12:57

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 00:39:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:39:25
Data point term sent to Coder	System	05 Nov 2020 22:54:49
User entered 'ibuprofen'	Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'abdominal cramp pain'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '800'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'as needed (PRN)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un Mar 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:54:28

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
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 SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 22:56:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:56:26
Data point term sent to Coder	System	05 Nov 2020 22:55:51
User entered 'synthroid'	Dhwani Shah (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'hypothyroidism'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '200'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	11 Nov 2020 21:47:18
User entered 'Other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:22:09
Query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	11 Nov 2020 21:47:25
User entered empty; reason for change Data Entry Error	(b) (4)	11 Nov 2020 21:47:18
User opened query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:09:18
User entered 'mcg'	Dhwani Shah (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:16:05
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' answered with 'PER PT CONFIRMED AS NEEDED ' (Site from DM).	Dhwani Shah (b) (4)	18 Jan 2021 22:16:16
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:32:03
User entered 'as needed (PRN)'	Dhwani Shah (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un UNK 2014'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:54:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 22:56:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:56:27
Data point term sent to Coder	System	05 Nov 2020 22:55:51
User entered 'liothyronine'	Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'hypothyroidism'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '5'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	11 Nov 2020 21:47:34
User entered 'Other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 11:22:26
Query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 21:47:38
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 21:47:34
User opened query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:11:14
User entered 'mcg'	Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:16:51
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' answered with 'PER PT CONFIRMED AS NEEDED' (Site from DM).	Dhwani Shah (b) (4)	18 Jan 2021 22:16:28
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:32:18
User entered 'as needed (PRN)'	Dhwani Shah (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un UNK 2014'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:55:36

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
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 SODIUM, PRODUCTSYNONYM: LEVOXYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 22:57:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:57:25
Data point term sent to Coder	System	05 Nov 2020 22:56:51
User entered 'levoxyll'	Dhwani Shah (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'hypothyroidism'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '150'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	11 Nov 2020 21:47:47
	(b) (4)	
User entered 'Other (OTHER)'	Dhwani Shah (b) (4)	05 Nov 2020 22:56:14
	(b) (4)	

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:22:35
Query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	11 Nov 2020 21:47:50
User entered empty; reason for change Data Entry Error	(b) (4)	11 Nov 2020 21:47:47
User opened query 'Per CDM: The other specify selected as "MCG" (Micrograms) is one of the listed choices of the dose unit. Kindly, update the data field and keep other specify as blank. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:11:45
User entered 'mcg'	Dhwani Shah (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:17:14
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' answered with 'PER PT CONFIRMED AS NEEDED' (Site from DM).	Dhwani Shah (b) (4)	18 Jan 2021 22:16:38
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:32:40
User entered 'as needed (PRN)'	Dhwani Shah (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un UNK 2014'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:56:14

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:58:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:58:23
Data point term sent to Coder	System	05 Nov 2020 22:57:53
User entered 'Naproxen'	Dhwani Shah (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the BODY ACHES (MYALGIA) is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES (MYALGIA) did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:47:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the BODY ACHES (MYALGIA) is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES (MYALGIA) did not meet the AE reporting criteria.' answered with 'CONFIRMED NO SEPRATE AE NEED TO CREATE' (Site from DM).	Dhwani Shah (b) (4)	18 Jan 2021 22:17:04

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the BODY ACHES (MYALGIA) is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES (MYALGIA) did not meet the AE reporting criteria.' (Site from DM). User entered 'body aches'	(b) (4), (b) (6)	21 Dec 2020 14:33:31
	Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '500'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'once (ONCE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it is prior to the start date of the noted symptom in the diary. Please reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:58:23
Query 'Per DM CLR: Please review the start/stop date of this medication as it is prior to the start date of the noted symptom in the diary. Please reconcile and update as appropriate, otherwise clarify.' answered with 'CONFIRMED AS IT IS' (Site from DM).	Dhwani Shah (b) (4)	18 Jan 2021 22:18:31
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it is prior to the start date of the noted symptom in the diary. Please reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:35:13
User entered '01 Nov 2020'	Dhwani Shah (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '01 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User entered empty.	System	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User entered empty.	System	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:45
User entered empty.	System	05 Nov 2020 22:56:56

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 05:56:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 05:56:29
Data point term sent to Coder	System	05 Nov 2020 22:57:53
User entered 'Naproxen'	Dhwani Shah (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the LOW GRADE FEVER, INJECTION ARM PAIN is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of LOW GRADE FEVER, INJECTION ARM PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:47:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the LOW GRADE FEVER, INJECTION ARM PAIN is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of LOW GRADE FEVER, INJECTION ARM PAIN did not meet the AE reporting criteria.' answered with 'CONFIRMED NO SEPRATE AE NEED TO CREATE' (Site from DM).	Dhwani Shah (b) (4)	18 Jan 2021 22:17:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the LOW GRADE FEVER, INJECTION ARM PAIN is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of LOW GRADE FEVER, INJECTION ARM PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:34:50
User entered 'Low grade fever/Fatigue/injection arm pain'	Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '500'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'once (ONCE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '01 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '01 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User entered empty.	System	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User entered empty.	System	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:47
User entered empty.	System	05 Nov 2020 22:57:45

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 09:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 09:51:44
Data point term sent to Coder	System	08 Feb 2021 17:13:42
User entered 'METRONIDAZOLE'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:30
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:31
User entered 'WORSENING OF DIVERTICULITIS'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:34
User entered '500'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:36
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:37
User entered empty.	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:40
User entered 'twice daily (BID)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:42
User entered empty.	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:44
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:46
User entered empty.	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:48
User entered '22 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:51
User entered '0'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:52
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:57
User entered '04 Feb 2021'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:44:59
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User entered '2'	System	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User entered '1'	System	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:50
User entered '804 (804)'	System	08 Feb 2021 17:13:30

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:49:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:49:43
Data point term sent to Coder	System	08 Feb 2021 17:14:43
User entered 'CIPROFLOXACIN'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:15
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:17
User entered 'WORSENING DIVERTICULITIS'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:19
User entered '500'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:22
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:23
User entered empty.	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:26
User entered 'twice daily (BID)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:27
User entered empty.	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:29
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:31
User entered empty.	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:33
User entered '22 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:35
User entered '0'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:37
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:39
User entered '04 Feb 2021'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:45:41
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User entered '2'	System	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User entered 'I'	System	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:52
User entered '804 (804)'	System	08 Feb 2021 17:14:21

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
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)	09 Feb 2021 20:54:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 20:54:44
Data point term sent to Coder	System	09 Feb 2021 20:53:35
User entered 'influenza vaccine'	Dhwani Shah (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'flu prophylaxis'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0.5'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mL (mL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'once (ONCE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '15 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '15 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User entered empty.	System	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User entered empty.	System	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:57
User entered empty.	System	09 Feb 2021 20:52:59

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 22:11:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 22:11:37
Data point term sent to Coder	System	09 Feb 2021 20:54:41
User entered 'ciprofloxacin'	Dhwani Shah (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'left ear infection'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '500'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'twice daily (BID)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '09 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '15 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User entered '2'	System	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User entered 'I'	System	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:58
User entered '804 (804)'	System	09 Feb 2021 20:53:43

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Feb 2021 20:55:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 20:55:37
Data point term sent to Coder	System	09 Feb 2021 20:54:42
User entered 'alprazolem'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'anxiety'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0.5'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un Feb 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Feb 2021 20:54:16

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OTHER DRUGS FOR CONSTIPATION, PRODUCT: LINACLOTIDE, PRODUCTSYNONYM: LINZESS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Feb 2021 20:56:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 20:56:37
Data point term sent to Coder	System	09 Feb 2021 20:55:43
User entered 'linzess'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'chronic consipation'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '145'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'ug (ug)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'as needed (PRN)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un Jan 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 20:55:05

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Feb 2021 13:58:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 13:58:47
Data point term sent to Coder	System	09 Feb 2021 20:56:45
User entered 'naproxen'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'abdominal cramp pain'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '500'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'as needed (PRN)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un Jan 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 20:55:55

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
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: ERGOCALCIFEROL, PRODUCTSYNONYM: VITAMIN D2 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Feb 2021 20:58:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 20:58:36
Data point term sent to Coder	System	09 Feb 2021 20:57:46
User entered 'vitamin d2'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'vitamin d deficiency'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '50000'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'IU (IU)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'every week (QS)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un UNK 2013'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	09 Feb 2021 20:56:46

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
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.	(b) (4) Coder Import (b) (4)	09 Feb 2021 20:58:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 20:58:37
Data point term sent to Coder	System	09 Feb 2021 20:57:46
User entered 'levothyroxine'	Dhwani Shah (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'hypothyroidism'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '150'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'ug (ug)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'un UNK 2013'	(b) (4) Dhwani Shah (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Feb 2021 20:57:22

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:27:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:27:17
Data point term sent to Coder	System	29 Mar 2021 21:03:06
User entered 'AMOXICILLIN'	Dhwani Shah (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'WORSENING DIVERTICULITIS'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	12 Apr 2021 11:42:16
	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
	(b) (4)	
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	07 Apr 2021 18:41:10
	(b) (4)	
User entered '875' reason for change: Data Entry Error	Dhwani Shah (b) (4)	07 Apr 2021 18:40:50
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User entered '825'	(b) (4), (b) (6)	07 Apr 2021 04:23:04
	Dhwani Shah (b) (4)	29 Mar 2021 21:02:12
	(b) (4)	

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'twice daily (BID)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '12 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered '26 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User entered '2'	System	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User entered 'I'	System	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:03:04
User entered '804 (804)'	System	29 Mar 2021 21:02:12

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:13:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:03:54
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:46:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:56:32
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	03 Oct 2020 16:00:30

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:13:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:48:05
User entered '21 Jan 2021'	Dhwani Shah (b) (4)	19 Feb 2021 22:56:49
	(b) (4)	

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:13:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:48:06
User entered 'CT SCAN'	Dhwani Shah (b) (4)	19 Feb 2021 22:56:49
	(b) (4)	

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:48:08
User entered 'Adverse Event (AE)'	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:56:49

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:13:36

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:48:10
User entered empty.	Dhwani Shah (b) (4)	19 Feb 2021 22:56:49
	(b) (4)	

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:13:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 00:05:48
User closed query 'Please confirm date. Per medical records, Abdominal Xray was done on 22Jan2021. ' (Site from CRA).		10 Mar 2021 00:05:45
Query 'Please confirm date. Per medical records, Abdominal Xray was done on 22Jan2021. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:38:00
User entered '22 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:37:54
User opened query 'Please confirm date. Per medical records, Abdominal Xray was done on 22Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 19:47:49
User entered '21 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:57:06

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:13:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:47:54
User entered 'ABDOMINAL X RAY VIEW'	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:57:06

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:13:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:47:55
User entered 'Adverse Event (AE)'	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:57:06

US3562205

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:13:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:52
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:47:57
User entered empty.	Dhwani Shah (b) (4) (b) (4)	19 Feb 2021 22:57:06

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered 'USA-US071-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Joseph'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered 'Davis'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered '3900 E Camel Back road'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Phoenix'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered '85018'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		09 Feb 2021 13:23:31
User entered 'US'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Feb 2021 18:12:31
User entered '3'	System	10 Feb 2021 17:08:10
User entered '2'	System	09 Feb 2021 13:23:41
User entered '1'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'USA-US071-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Joseph'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Davis'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered '3900 E Camel Back road'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Phoenix'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered '85018'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:23:31
User entered 'US'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Feb 2021 18:12:31
User entered '3'	System	10 Feb 2021 17:08:10
User entered '2'	System	09 Feb 2021 13:23:41
User entered '1'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
User entered '26/Jan/2021 12:56'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:13:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:23:31
User entered 'l'		26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'USA-US071-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered 'Joseph'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Davis'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered '3900 E Camel Back road'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Phoenix'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered '85018'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		09 Feb 2021 13:23:31
User entered 'US'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Feb 2021 18:12:31
User entered '3'	System	10 Feb 2021 17:08:10
User entered '2'	System	09 Feb 2021 13:23:41
User entered '1'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
User entered '09/Feb/2021 13:23'	System	09 Feb 2021 13:23:41

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:13:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:12:10
User entered 'l'		09 Feb 2021 13:23:41

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'USA-US071-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Joseph'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Davis'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered '3900 E Camel Back road'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Phoenix'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered '85018'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:23:31
User entered 'US'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Feb 2021 18:12:31
User entered '3'	System	10 Feb 2021 17:08:10
User entered '2'	System	09 Feb 2021 13:23:41
User entered '1'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
User entered '10/Feb/2021 12:08'	System	10 Feb 2021 17:08:10

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:13:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:12:10
User entered 'l'		10 Feb 2021 17:08:10

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:56:37
User entered 'USA-US071-2021-MRNA-1273-P301000004'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Yes (Y)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'No (N)'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Joseph'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Davis'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered '3900 E Camel Back road'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered 'Phoenix'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		26 Jan 2021 17:56:37
User entered '85018'	System	26 Jan 2021 17:56:24

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
Reviewed for Safety.		09 Feb 2021 13:23:31
User entered 'US'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Feb 2021 18:12:31
User entered '3'	System	10 Feb 2021 17:08:10
User entered '2'	System	09 Feb 2021 13:23:41
User entered '1'	System	26 Jan 2021 17:56:44

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:18:12
User entered '22/Feb/2021 13:12'	System	22 Feb 2021 18:12:31

US3562205

Folder: SAE USA-US071-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:13:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:09:03
DataPoint Verified.	(b) (4)	23 Feb 2021 18:18:12
User entered 'l'	(b) (4), (b) (6)	22 Feb 2021 18:12:31