

US3582154 (Prod: Kaiser Permanente - Seattle)

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:01:28

All time stamps listed in this document are displayed in GMT

US3582154

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 00:23:01

Generated On: 11 Aug 2021 23:01:28

Participant ID

US3582154

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

US3582154

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:23:03

Generated On: 11 Aug 2021 23:01:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3582154

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Date of Informed Consent (*dd MMM yyyy*) 18 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3582154

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:23:03

Generated On: 11 Aug 2021 23:01:28

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

Condition	CERVICAL DYSPHASIA
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)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

Condition	SULFITE ALLERGY
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)	_____

US3582154

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

Condition	MUSCLE PAIN FROM ACTIVITY (GENERALIZED)
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3582154

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

Condition	HUMAN PAPILLOMA VIRUS TEST POSITIVE
Start date (dd MMM yyyy)	UN UNK 2010
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)	16 OCT 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	OCT 2018
Stop Year (derived)	2018

US3582154

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

Condition	HIVES
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)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

Condition	BOTOX INJECTION (UPPER LIP)
Start date (dd MMM yyyy)	21 AUG 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)	21 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 19:30:04

Generated On: 11 Aug 2021 23:01:28

Condition	JUVEDERM (UPPER AND LOWER LIP)
Start date (dd MMM yyyy)	04 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)	11 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

US3582154

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:23:03

Generated On: 11 Aug 2021 23:01:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:47 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:47
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	176.4 lb
BMI (<i>xxx.x</i>)	26.10419 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:23:03

Generated On: 11 Aug 2021 23:01:28

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Date of assessment (*dd MMM yyyy*) 18 SEP 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:23:03

Generated On: 11 Aug 2021 23:01:28

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 18 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:23:03

Generated On: 11 Aug 2021 23:01:28

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:23:03

Generated On: 11 Aug 2021 23:01:28

WORKS IN CHILD WELFARE OFFICE & IN CONTACT WITH COMMUNITY MEMBERS, STAFF & COLLEAGUES. CHILDREN IN CHILD CARE, WORKS FACE TO FACE WITH CUSTOMERS. SON IN SOCCER, FAMILY GOES TO RESTAURANTS.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

What was the date of randomization? (dd MMM yyyy) 18 SEP 2020

What was the participant's randomization number? 114666

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

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 (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:47 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:47
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	11 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:11 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 15:11
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

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.

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 23:20:47

Generated On: 11 Aug 2021 23:01:28

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) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 14:39 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 14:39

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	18 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:00 (24 HR)
Collection date and time (derived)	18 SEP 2020 14:00

US3582154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:23:03

Generated On: 11 Aug 2021 23:01:28

Collection date (<i>dd MMM yyyy</i>)	18 SEP 2020		
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:12	18 SEP 2020 14:12
Nasopharyngeal Swab 2	No		

US3582154

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp 18 SEP 2020 15:14
PC Open Date & Time 18 SEP 2020 14:59
PC Close Date & Time 18 SEP 2020 17:29

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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 98.7 °F

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

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

PC Time Stamp 18 SEP 2020 18:27
PC Open Date & Time 18 SEP 2020 18:24
PC Close Date & Time 19 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 01:23
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

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	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 20:10
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 SEP 2020 19:17
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 SEP 2020 21:02
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 20:17
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 SEP 2020 19:24
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

18 SEP 2020 15:15

PC Open Date & Time

18 SEP 2020 14:59

PC Close Date & Time

18 SEP 2020 17:29

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

18 SEP 2020 18:28

PC Open Date & Time

18 SEP 2020 18:24

PC Close Date & Time

19 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 2

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

19 SEP 2020 12:35

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 3

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

20 SEP 2020 20:09

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

21 SEP 2020 19:18

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 5

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	22 SEP 2020 21:02
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 6

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

23 SEP 2020 20:18

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 7

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

24 SEP 2020 19:24

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

No

Yes

PC Time stamp	18 SEP 2020 15:15
PC Open Date & Time	18 SEP 2020 14:59
PC Close Date & Time	18 SEP 2020 17:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

No

Yes

PC Time stamp	18 SEP 2020 18:28
PC Open Date & Time	18 SEP 2020 18:24
PC Close Date & Time	19 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 01:23
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 20:09
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	21 SEP 2020 19:18
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 21:02
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 20:18
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 19:23
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3582154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

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)	14 OCT 2020
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 09:22
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

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)	14 OCT 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 10:26
Temperature (xxx.x)	99.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3582154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 14 OCT 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

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) 14 OCT 2020

What was the treatment time? (00:00-23:59) 09:55 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 09:55

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

US3582154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 OCT 2020

Collection time (*00:00-23:59*) 09:41 (24 HR)

Collection date and time (derived) 14 OCT 2020 09:41

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Collection date (<i>dd MMM yyyy</i>)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:45	14 OCT 2020 09:45
Nasopharyngeal Swab 2	No		

US3582154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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 99.8 °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 14 OCT 2020 10:30

PC Open Date & Time 14 OCT 2020 10:15

PC Close Date & Time 14 OCT 2020 12:45

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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 98.1 °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 14 OCT 2020 18:34
PC Open Date & Time 14 OCT 2020 13:40
PC Close Date & Time 15 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

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

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

PC Time Stamp 16 OCT 2020 06:14

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE in °F**
Was any **MEDICATION TAKEN today for pain or fever?** Yes
No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 16 OCT 2020 12:00
PC Close Date & Time 17 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

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	18 OCT 2020 10:11
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 OCT 2020 20:21
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 OCT 2020 05:34
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 OCT 2020 21:07
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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	14 OCT 2020 10:30
PC Open Date & Time	14 OCT 2020 10:15
PC Close Date & Time	14 OCT 2020 12:45

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

14 OCT 2020 18:35

PC Open Date & Time

14 OCT 2020 13:40

PC Close Date & Time

15 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 2

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	16 OCT 2020 06:14
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 4

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

18 OCT 2020 10:10

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 5

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

18 OCT 2020 20:21

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 6

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

20 OCT 2020 05:34

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 7

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

20 OCT 2020 21:14

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

No
Yes

PC Time stamp	14 OCT 2020 10:31
PC Open Date & Time	14 OCT 2020 10:15
PC Close Date & Time	14 OCT 2020 12:45

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

No

Yes

PC Time stamp	14 OCT 2020 18:35
PC Open Date & Time	14 OCT 2020 13:40
PC Close Date & Time	15 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	16 OCT 2020 06:13
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

Yes

PC Time stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	18 OCT 2020 10:10
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	18 OCT 2020 20:20
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	20 OCT 2020 05:35
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

	Yes <input type="checkbox"/>
PC Time stamp	20 OCT 2020 21:14
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3582154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:23:13

Generated On: 11 Aug 2021 23:01:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:23:13

Generated On: 11 Aug 2021 23:01:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	08:07 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 08:07
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3582154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

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.

US3582154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 11 NOV 2020

Collection time (*00:00-23:59*) 08:20 (24 HR)

Collection date and time (derived) 11 NOV 2020 08:20

US3582154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:12

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	_____
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 <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"/>

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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	03 DEC 2020 10:55:19
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 DEC 2020 07:40:01
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 DEC 2020 09:00:52
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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
Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 15:25:42
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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	03 JAN 2021 08:16:16
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 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 JAN 2021 12:08:54
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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	17 JAN 2021 07:58:33
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 06:08:30
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 <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	31 JAN 2021 09:42:02
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 FEB 2021 07:38:12
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 FEB 2021 07:01:44
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 <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 FEB 2021 19:16:42
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 07 MAR 2021 07:01:38

Patient Cloud Open Date & Time 07 MAR 2021 00:01

Patient Cloud Close Date & Time 11 MAR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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	14 MAR 2021 16:11:05
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 <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 MAR 2021 05:57:11
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 14:35:20
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 06:29:47
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 04:26:38
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 APR 2021 06:59:59
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 06:43:54
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 MAY 2021 10:34:11
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 236

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 243

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

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	03 JUN 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	29 AUG 2021 00:01
Patient Cloud Close Date & Time	02 SEP 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#) 16 SEP 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	07 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	02 DEC 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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
Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

Patient Cloud Open Date & Time	09 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 488

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#) 28 APR 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	08 MAY 2022 00:01
Patient Cloud Close Date & Time	12 MAY 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	26 MAY 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	29 MAY 2022 00:01
Patient Cloud Close Date & Time	02 JUN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 691

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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
Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#) 29 SEP 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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
Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	03 NOV 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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°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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 Yes

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

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3582154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:01:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	05 MAR 2021 11:40:36

US3582154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 08 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 APR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT4

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3582154

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

05 APR 2021

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

US3582154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 APR 2021

Collection time (*00:00-23:59*) 14:45 (24 HR)

Collection date and time (derived) 05 APR 2021 14:45

US3582154

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

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 _____

US3582154

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3582154

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:01:28

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"/>

US3582154

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 23:01:28

Generate Next COVID-19 Assessment

Yes

No

US3582154

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 03 FEB 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3582154

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Date of updated informed consent (<i>dd MMM yyyy</i>)	03 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	03 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3582154

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

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

US3582154

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 MAR 2021
Time of assessment (00:00-23:59)	11:04 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 11:04
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3582154

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 MAR 2021
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 12:03
Temperature (xxx.x)	97.4 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)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3582154

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

05 MAR 2021

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

US3582154

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

Form: Pregnancy Test

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 05 MAR 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3582154

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

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

What was the treatment date? (dd MMM yyyy) 05 MAR 2021

What was the treatment time? (00:00-23:59) 11:33 (24 HR)

Treatment Date and Time (derived) 05 MAR 2021 11:33

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

US3582154

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 03 FEB 2021

Collection time (*00:00-23:59*) 10:29 (24 HR)

Collection date and time (derived) 03 FEB 2021 10:29

US3582154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 03 FEB 2021

Collection time (*00:00 - 23:59*) 10:36

Collection Date and Time (derived) 03 FEB 2021 10:36

US3582154

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 12 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3582154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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	OLD29

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

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)	05 APR 2021
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 14:30
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

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 (<i>dd MMM yyyy</i>)	05 APR 2021
Time of assessment (<i>00:00-23:59</i>)	15:44 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 15:44
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3582154

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

05 APR 2021

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

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 05 APR 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3582154

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 05 APR 2021

What was the treatment time? (00:00-23:59) 15:14 (24 HR)

Treatment Date and Time (derived) 05 APR 2021 15:14

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

What was the frequency of the study treatment dosing? ONCE

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

US3582154

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 10 Apr 2021 18:31:31

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3582154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

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 _____

US3582154

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3582154

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

AEID

Adverse event HEADACHE, RIGHT FRONTAL MILD

Was this a medically-attended AE? Yes No

Was this a Solicited Adverse Reaction? Yes No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes No

Start date (dd MMM yyyy) 24 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes No

If not Ongoing, end date (dd MMM yyyy) 25 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

AEID	
Adverse event	URTICARIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply) None

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

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) 0

Admitted to ICU Derived (CSA Programming Field Only) _____

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

AEID

Adverse event NASAL CONGESTION

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 14 OCT 2020

Start time (00:00-23:59) 04:00 (24 HR)

AE start date and time (derived) 14 OCT 2020 04:00

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 15 OCT 2020

End time (00:00-23:59) 08:00 (24 HR)

AE End Date and Time (derived) 15 OCT 2020 08:00

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

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) 0

Admitted to ICU Derived (CSA Programming Field Only) _____

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	16 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

AEID

Adverse event

NASAL CONGESTION,
INTERMITTENT

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

23 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

AEID

Adverse event

GINGIVAL INFLAMMATION
DUE TO BRACKET OF BRACES.
RIGHT UPPER TOOTH (#3)

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

2 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

8 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

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	
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)	

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

AEID	
Adverse event	SINUS CONGESTION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

AEID

Adverse event

POST NASAL DRAINAGE

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

24 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

26 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Mar 2021 17:17:05

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 00:23:02

Generated On: 11 Aug 2021 23:01:28

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

Yes

No

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

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication NUVARING

Prophylaxis Yes
No

Indication BIRTH CONTROL

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify RING

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input checked="" type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
	If route of administration is Other, specify	
	Start date (dd MMM yyyy)	UN UNK 2014
	Start date completely unknown	False
	Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
	If not Ongoing, End date (dd MMM yyyy)	30 NOV 2020
	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 checked="" type="radio"/> 803 <input type="radio"/> 804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication SALINE NASAL MIST

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 SPRAY

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input checked="" 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) _____

Start date completely unknown True

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication CETIRIZINE

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 14 JUL 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication FLONASE

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 50

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 22:03:39

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- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify GUMMIES

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

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 JUL 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 01 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication HEADACHE OR MUSCLE PAIN
FROM ACTIVITY

Dose per administration 400

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) _____

Start date completely unknown True

Ongoing? Yes No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication AFRIN 0.05%
[OXYMETAZOLINE]

Prophylaxis Yes
No

Indication NASAL CONGESTION

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify SPRAY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" 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) 14 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 15 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication ZICAM RAPID MELTS:
INGREDIENTS-ZINC ACETATE,
ZINC GLUCONATE

Prophylaxis Yes
No

Indication NASAL CONGESTION

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 5X/D

Route of administration Oral
Topical
Subcutaneous
Transdermal

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US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

	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 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 23 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication GINGIVAL INFLAMMATION
FROM BRACES BRACKET.
RIGHT UPPER TOOTH #3

Dose per administration 400

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

	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) 2 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 4 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication CHLORHEXIDINE GLUCONATE
0.12%

Prophylaxis Yes
No

Indication GINGIVAL INFLAMMATION
DUE TO BRACES BRACKET
RIGHT UPPER TOOTH #3

Dose per administration 15

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

390 of 2332

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>

If route of administration is Other, specify	ORAL RINSE
--	------------

Start date (dd MMM yyyy)	5 NOV 2020
--------------------------	------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy)	
--	--

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

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)

392 of 2332

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

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*) 09 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 09 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3582154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 22:03:39

Generated On: 11 Aug 2021 23:01:28

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3582154

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:01:28

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

US3582154

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:01:28

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Other

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

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes

No

Unknown

Audit

US3582154 (Prod: Kaiser Permanente - Seattle)

US3582154

Form: Participant Creation

Generated On: 11 Aug 2021 23:01:28

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:23:18
User entered 'US3582154'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:24:11

US3582154

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:18
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:15:43

US3582154

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:18
User entered '18 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:24:12

US3582154

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:18
User entered 'Clinic (Clinic)'	Stella Lee (b) (4)	21 Sep 2020 22:15:43

US3582154

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'SCRN'	System	21 Sep 2020 22:15:43

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:24:13

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered '29'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'YEARS'	System	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '29'	System	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered 'Female (F)'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered 'l'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:28

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:38
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:10

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:43
User entered '18 Sep 2020'	Lynn Gross (b) (4)	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Sep 2020'	System	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2020'	System	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:43
User entered 'Amendment 3 (3)'	Lynn Gross (b) (4)	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:43
User entered 'Yes (Y)'	Lynn Gross (b) (4)	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:43
User entered empty.	Lynn Gross (b) (4)	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:43
User entered empty.	Lynn Gross (b) (4)	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:43
User entered 'No (N)'	Lynn Gross (b) (4)	18 Sep 2020 21:46:34

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:43
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:24:12

US3582154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:01:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'l'	System	18 Sep 2020 21:46:50

US3582154

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:46
User entered 'Yes (Y)'	Lynn Gross (b) (4)	18 Sep 2020 21:46:50

US3582154

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 23:01:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:50
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:16:19

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User coded data point as SOC: Reproductive system and breast disorders, HLG: Cervix disorders (excl infections and inflammations), HLT: Cervix disorders NEC, PT: Cervical dysplasia, LLT: Cervical dysplasia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:05:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:05:51
Data point term sent to Coder	System	21 Sep 2020 22:16:52
User entered 'Cervical dysphasia'	Stella Lee (b) (4)	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'UN UNK 2010'	Stella Lee (b) (4)	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Jan 2010'	System	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2010'	System	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:16:37

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:18:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:18:49
Data point term sent to Coder	System	21 Sep 2020 22:17:54
User entered 'Seasonal allergies'	Stella Lee (b) (4)	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'UN UNK 2006'	Stella Lee (b) (4)	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Jan 2006'	System	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2006'	System	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:16:53

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 12:21:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 12:21:19
Data point term sent to Coder	System	21 Sep 2020 22:17:52
User entered 'Sulfite allergy'	Stella Lee (b) (4)	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'UN UNK 2015'	Stella Lee (b) (4)	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Jan 2015'	System	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2015'	System	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:36

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:18:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:18:49
Data point term sent to Coder	System	21 Sep 2020 22:17:55
User entered 'Headache'	Stella Lee (b) (4)	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'l'	Stella Lee (b) (4)	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:46

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 06:46:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 06:46:11
User closed query 'Per DM CLR-RQ: It was noted in the response that location is generalized. Please update to include "GENERALIZED" in the condition MUSCLE PAIN. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 04:40:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
Data point term sent to Coder	System	12 Nov 2020 00:07:23
Query 'Per DM CLR-RQ: It was noted in the response that location is generalized. Please update to include "GENERALIZED" in the condition MUSCLE PAIN. Update as appropriate.' answered with 'updated' (Site from DM).	Melissa Scheer (b) (4)	12 Nov 2020 00:07:10
Coding entries removed.	Melissa Scheer (b) (4)	12 Nov 2020 00:07:02
User entered 'MUSCLE PAIN FROM ACTIVITY (generalized)' reason for change: Per Query Resolution	Melissa Scheer (b) (4)	12 Nov 2020 00:07:02
User opened query 'Per DM CLR-RQ: It was noted in the response that location is generalized. Please update to include "GENERALIZED" in the condition MUSCLE PAIN. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:46:49
User closed query 'Per DM CLR RQ: Thank you for the response; kindly Update MH term with the specific location of MUSCLE PAIN.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:29:45
Query 'Per DM CLR RQ: Thank you for the response; kindly Update MH term with the specific location of MUSCLE PAIN.' answered with 'Per chart after talking to patient the pain is generalized, usually after weight lifting. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:24:06

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR RQ: Thank you for the response; kindly Update MH term with the specific location of MUSCLE PAIN.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:38:50
User closed query 'Per DM CLR: Please specify the location and/or type of MUSCLE PAIN (arms, legs, generalized, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:38:50
Query 'Per DM CLR: Please specify the location and/or type of MUSCLE PAIN (arms, legs, generalized, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'generalized muscle pain from heavy exercise and weight lifting' (Site from DM).	Lynn Gross (b) (4)	29 Oct 2020 17:47:47
User opened query 'Per DM CLR: Please specify the location and/or type of MUSCLE PAIN (arms, legs, generalized, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:58:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle pain - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 05:40:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 05:40:46
Data point term sent to Coder System	System	21 Sep 2020 22:18:55
User entered 'Muscle pain from activity'	Stella Lee (b) (4)	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'l'	Stella Lee (b) (4)	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	21 Sep 2020 22:17:57

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: Human papilloma virus test positive, LLT: Human papilloma virus test positive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:19:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:19:51
Data point term sent to Coder	System	21 Sep 2020 22:18:55
User entered 'Human papilloma virus test positive'	Stella Lee (b) (4)	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'UN UNK 2010'	Stella Lee (b) (4)	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 00:21:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Un-verified.	(b) (4) Marilyn Nguyen (b) (4)	04 Feb 2021 21:48:26
User entered 'No (N)' reason for change: New Information	(b) (4) Marilyn Nguyen (b) (4)	04 Feb 2021 21:48:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4)	04 Mar 2021 00:22:00
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Un-verified.	(b) (4)	(b) (4)
	Marilyn Nguyen (b) (4)	04 Feb 2021 21:48:26
User entered '16 Oct 2018' reason for change: New Information	(b) (4)	(b) (4)
	Marilyn Nguyen (b) (4)	04 Feb 2021 21:48:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Jan 2010'	System	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2010'	System	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Oct 2018'	System	04 Feb 2021 21:48:26
User entered empty.	System	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2018'	System	04 Feb 2021 21:48:26
User entered empty.	System	21 Sep 2020 22:18:37

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:57:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:57:57
Data point term sent to Coder	System	01 Oct 2020 19:57:04
User entered 'hives'	Vi Tran (b) (4) (b) (4)	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'un UNK 2015'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered 'Yes (Y)'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:28:54
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Jan 2015'	System	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2015'	System	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	01 Oct 2020 19:56:35

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:41
User coded data point as SOC: Surgical and medical procedures, HLG: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Mar 2021 16:25:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Mar 2021 16:25:49
Data point term sent to Coder	System	05 Mar 2021 19:48:11
User entered 'Botox injection (upper lip)'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:48
User entered '21 Aug 2020'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:51
User entered '0'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:56
User entered 'No (N)'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:59
User entered '21 Aug 2020'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:29:04
User entered '0'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Aug 2020'	System	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2020'	System	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Aug 2020'	System	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2020'	System	05 Mar 2021 19:48:05

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 04:39:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 04:39:25
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Lip therapeutic procedures, PT: Lip cosmetic procedure, LLT: Lip cosmetic procedure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 12:17:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 12:17:49
Data point term sent to Coder	System	05 Mar 2021 19:49:11
User entered 'Juvederm (upper and lower lip)'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:04
User entered '04 Sep 2020'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:02
User entered '0'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:28:00
User entered 'No (N)'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:27:58
User entered '11 Sep 2020'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:27:56
User entered '0'	Melissa Scheer (b) (4) (b) (4)	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Sep 2020'	System	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2020'	System	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'Sep 2020'	System	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '2020'	System	05 Mar 2021 19:48:48

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered '18 Sep 2020'	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered '13:47'	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '18 Sep 2020 13:47'	System	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered '69' in DataPoint set to visible.	Stella Lee (b) (4) System	21 Sep 2020 22:19:15 18 Sep 2020 21:46:50

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered '176.4' lb	Stella Lee (b) (4)	21 Sep 2020 22:19:15
DataPoint set to visible.	System	18 Sep 2020 21:46:50

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '26.10419'	System	21 Sep 2020 22:19:15
DataPoint set to visible.	System	18 Sep 2020 21:46:50

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'kg/m2'	System	21 Sep 2020 22:19:15
DataPoint set to visible.	System	18 Sep 2020 21:46:50

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'bpm'	System	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'breaths/min'	System	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'mmHg'	System	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:33
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'mmHg'	System	21 Sep 2020 22:19:15

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17

US3582154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17

US3582154

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:38
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:20:04

US3582154

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:38
User entered '18 Sep 2020'	Stella Lee (b) (4)	21 Sep 2020 22:20:04

US3582154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:49
User entered '18 Sep 2020'	Stella Lee (b) (4)	21 Sep 2020 22:20:33

US3582154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:49
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:20:33

US3582154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:01:28

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:49
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:20:33

US3582154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:01:28

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:49
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:20:33

US3582154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:49
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:20:33

US3582154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:01:28

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:49
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:20:33

US3582154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:49
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:20:33

US3582154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:01:28

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:30:49
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:20:33

US3582154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:08:32
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:39

US3582154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:08:32
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '18 Sep 2020'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:39

US3582154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:08:32
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Urine (URINE)'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:39

US3582154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:08:32
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Negative (NEGATIVE)'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:39

US3582154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:08:32
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'No (N)'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:39

US3582154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:08:32
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:39

US3582154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:08:32
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:39

US3582154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	13 Nov 2020 01:18:39

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:45:02
User closed query 'Please verify. Per source, this box is not marked.' (Site from CRA).	(b) (4), (b) (6)	30 Nov 2020 23:43:49
Query 'Please verify. Per source, this box is not marked.' answered with 'updated' (Site from CRA).	Roxanne Erolin (b) (4)	13 Nov 2020 20:23:33
DataPoint Un-verified.	(b) (4) Roxanne Erolin (b) (4)	13 Nov 2020 20:23:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Roxanne Erolin (b) (4)	13 Nov 2020 20:23:26
User opened query 'Please verify. Per source, this box is not marked.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 21:36:59
DataPoint Verified.	(b) (4)	12 Nov 2020 21:36:14
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'Works in child welfare office & in contact with community members, staff & colleagues. Children in child care, works face to face with customers. Son in soccer, family goes to restaurants.'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '0'	(b) (4) Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered 'l'	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '0'	(b) (4) Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:36:14
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:22:45

US3582154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:25
User entered 'Yes (Y)'	Lynn Gross (b) (4)	18 Sep 2020 21:44:47

US3582154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:25
User entered '18 Sep 2020'	Lynn Gross (b) (4)	18 Sep 2020 21:44:47

US3582154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[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 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:25
User entered 'Clinic (Clinic)'	Lynn Gross (b) (4)	18 Sep 2020 21:44:47

US3582154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'VISIT1'	System	18 Sep 2020 21:44:47

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered '18 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 21:24:11

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered '114666'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 21:24:11

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 21:24:11

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

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 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:15:30

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

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 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:15:30

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:15:30

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:15:30

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:15:30

US3582154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:32
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:15:30
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:33:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:33:07

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:23:21

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:23:21

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:23:21

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '18 Sep 2020'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '13:47'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '18 Sep 2020 13:47'	System	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '97.7' F	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered 'Other (Other)'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered 'Temporal'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

b

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '80'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'bpm'	System	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '11'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'breaths/min'	System	21 Sep 2020 22:23:21

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '132'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	21 Sep 2020 22:23:21

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '77'	Stella Lee (b) (4)	21 Sep 2020 22:23:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	21 Sep 2020 22:23:21

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:23:21

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered missing code ND - Not Done.	Stella Lee (b) (4)	21 Sep 2020 22:23:21

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User accepted default value 'Post-Dose (POSTDOSE)'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '18 Sep 2020'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '15:11'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '18 Sep 2020 15:11'	System	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '98.6' F	Stella Lee (b) (4)	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered 'Oral (Oral)'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '84'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'bpm'	System	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '12'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'breaths/min'	System	21 Sep 2020 22:23:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '119'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:37:40
User entered '64'	Stella Lee (b) (4)	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	21 Sep 2020 22:23:55

US3582154

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:04
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:24:01

US3582154

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:04
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:24:01

US3582154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	05 Mar 2021 23:20:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:57:27
User closed query 'This data was already entered under Screening. Please remove, enter no, per CCGs.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 17:57:23
Query 'This data was already entered under Screening. Please remove, enter no, per CCGs.' answered with 'removed per query, information collected under screening' (Site from CRA).	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:47:18
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 23:47:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 23:47:14
User entered 'No (N)' reason for change: Per Query Resolution	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:47:14
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 23:46:39
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User entered empty; reason for change Per Query Resolution	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User opened query 'This data was already entered under Screening. Please remove, enter no, per CCGs.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 21:09:28
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Un-verified.	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
User entered 'Yes (Y)' reason for change: Per Query Resolution	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:24:03
User closed query 'Please answer NO per CCGs and enter this data under screening.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 19:24:01
Query 'Please answer NO per CCGs and enter this data under screening.' answered with 'updated.' (Site from CRA).	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:17

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Roxanne Erolin (b) (4)	13 Nov 2020 01:18:10
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Roxanne Erolin (b) (4)	13 Nov 2020 01:18:10
	(b) (4)	
User opened query 'Please answer NO per CCGs and enter this data under screening. (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 21:35:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:44
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:24:40

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	05 Mar 2021 23:20:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:57:38
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User entered empty; reason for change Per Query Resolution	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Un-verified.	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
User entered '18 Sep 2020' reason for change: Per Query Resolution	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:24:03
DataPoint Un-verified.	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:10
User entered empty; reason for change Data Entry Error	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:44
User entered '18 Sep 2020'	Stella Lee (b) (4)	21 Sep 2020 22:24:40

US3582154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	05 Mar 2021 23:20:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:57:35
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User entered empty; reason for change Per Query Resolution	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Un-verified.	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
User entered 'Urine (URINE)' reason for change: Per Query Resolution	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:24:03
DataPoint Un-verified.	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:10
User entered empty; reason for change Data Entry Error	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:44
User entered 'Urine (URINE)'	Stella Lee (b) (4)	21 Sep 2020 22:24:40

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	05 Mar 2021 23:20:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:57:33
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User entered empty; reason for change Per Query Resolution	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Un-verified.	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
User entered 'Negative (NEGATIVE)' reason for change: Per Query Resolution	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:24:03
DataPoint Un-verified.	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:10
User entered empty; reason for change Data Entry Error	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:44
User entered 'Negative (NEGATIVE)'	Stella Lee (b) (4)	21 Sep 2020 22:24:40

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	05 Mar 2021 23:20:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:57:30
DataPoint Un-verified.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
User entered empty; reason for change Per Query Resolution	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:46:39
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:09:34
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
User closed query 'Per CDM: Please consider entering data as No. (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:27:46
Query 'Per CDM: Please consider entering data as No. answered with 'confirmed and updated' (Site from DM).	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:49
DataPoint Un-verified.	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
User entered 'No (N)' reason for change: Per Query Resolution	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:53:22
User opened query 'Per CDM: Please consider entering data as No. (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:33:25
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:24:03
DataPoint Un-verified.	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:10
User entered empty; reason for change Data Entry Error	Roxanne Erolin (b) (4) (b) (4)	13 Nov 2020 01:18:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:44
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:24:40

US3582154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:44
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:24:40

US3582154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:44
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:24:40

US3582154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered empty.	System	21 Sep 2020 22:24:40

US3582154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:20
User entered 'Yes (Y)'	Lynn Gross (b) (4)	18 Sep 2020 21:48:06

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:20
User entered empty.	Lynn Gross (b) (4)	18 Sep 2020 21:48:06

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

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 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:20
User entered empty.	Lynn Gross (b) (4)	18 Sep 2020 21:48:06

US3582154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 21:48:06

US3582154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:20
User entered '18 Sep 2020'	Lynn Gross (b) (4)	18 Sep 2020 21:48:06

US3582154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:20
User entered '14:39'	Lynn Gross (b) (4)	18 Sep 2020 21:48:06

US3582154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '18 Sep 2020 14:39'	System	18 Sep 2020 21:48:06

US3582154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:20
User entered 'Left Arm (LEFT ARM)'	Lynn Gross (b) (4)	18 Sep 2020 21:48:06

US3582154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:39:20
User entered 'ONCE'	System	18 Sep 2020 21:48:06

US3582154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 21:48:06

US3582154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:40:50
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:24:51

US3582154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:40:50
User entered '18 Sep 2020'	Stella Lee (b) (4)	21 Sep 2020 22:24:51

US3582154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:40:50
User entered '14:00'	Stella Lee (b) (4)	21 Sep 2020 22:24:51

US3582154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '18 Sep 2020 14:00'	System	21 Sep 2020 22:24:51

US3582154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:01:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:40:57
User entered '18 Sep 2020'	Stella Lee (b) (4)	21 Sep 2020 22:24:59

US3582154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stella Lee (b) (4)	21 Sep 2020 22:24:59

US3582154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:40:57
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:24:59

US3582154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:40:57
User entered '14:12'	Stella Lee (b) (4)	21 Sep 2020 22:24:59

US3582154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '18 Sep 2020 14:12'	System	21 Sep 2020 22:24:59

US3582154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:01:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stella Lee (b) (4)	21 Sep 2020 22:24:59

US3582154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:40:57
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:24:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:40:57
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:24:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered empty.	System	21 Sep 2020 22:24:59

US3582154

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:09:29

US3582154

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	28 Sep 2020 19:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:14:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '93bf3200-138b-4a37-a438-9a96b0df652f'	System	18 Sep 2020 22:14:55
User entered 'Yes (Y)'	System	18 Sep 2020 22:14:55

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:14:44', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '93bf3200-138b-4a37-a438-9a96b0df652f' User entered '98.6'	System	18 Sep 2020 22:14:55
	System	18 Sep 2020 22:14:55

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:14:47', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '93bf3200-138b-4a37-a438-9a96b0df652f'	System	18 Sep 2020 22:14:55
User entered 'No (N)'	System	18 Sep 2020 22:14:55

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:14:51', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '93bf3200-138b-4a37-a438-9a96b0df652f'	System	18 Sep 2020 22:14:55
User entered '18 Sep 2020 15:14'	System	18 Sep 2020 22:14:55

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 14:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 17:29'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:26:05', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a1bf9b6c-7360-4634-bc15-e51e6687f1ee'	System	19 Sep 2020 01:27:46
User entered 'Yes (Y)'	System	19 Sep 2020 01:27:46

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:27:34', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a1bf9b6c-7360-4634-bc15-e51e6687f1ee'	System	19 Sep 2020 01:27:46
User entered '98.7'	System	19 Sep 2020 01:27:46

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:27:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a1bf9b6c-7360-4634-bc15-e51e6687f1ee'	System	19 Sep 2020 01:27:46
User entered 'No (N)'	System	19 Sep 2020 01:27:46

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:27:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a1bf9b6c-7360-4634-bc15-e51e6687f1ee'	System	19 Sep 2020 01:27:46
User entered '18 Sep 2020 18:27'	System	19 Sep 2020 01:27:46

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 18:24'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 2'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:23:16', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '438f2f2b-bb50-497a-b0d5-a3d521e4f93f'	System	20 Sep 2020 08:23:35
User entered 'Yes (Y)'	System	20 Sep 2020 08:23:35

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:23:25', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '438f2f2b-bb50-497a-b0d5-a3d521e4f93f' User entered '97.8'	System	20 Sep 2020 08:23:35
	System	20 Sep 2020 08:23:35

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:23:29', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '438f2f2b-bb50-497a-b0d5-a3d521e4f93f'	System	20 Sep 2020 08:23:35
User entered 'No (N)'	System	20 Sep 2020 08:23:35

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:23:31', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '438f2f2b-bb50-497a-b0d5-a3d521e4f93f'	System	20 Sep 2020 08:23:35
User entered '20 Sep 2020 01:23'	System	20 Sep 2020 08:23:35

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 3'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:53', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1bba7e40-4fb2-4280-9e11-694d41e70cb5'	System	21 Sep 2020 03:10:12
User entered 'Yes (Y)'	System	21 Sep 2020 03:10:12

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:58', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1bba7e40-4fb2-4280-9e11-694d41e70cb5'	System	21 Sep 2020 03:10:12
User entered '97.8'	System	21 Sep 2020 03:10:12

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:10:01', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1bba7e40-4fb2-4280-9e11-694d41e70cb5'	System	21 Sep 2020 03:10:12
User entered 'No (N)'	System	21 Sep 2020 03:10:12

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:10:09', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1bba7e40-4fb2-4280-9e11-694d41e70cb5'	System	21 Sep 2020 03:10:12
User entered '20 Sep 2020 20:10'	System	21 Sep 2020 03:10:12

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 4'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:17:42', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74de8830-83e3-4850-bd61-d4d4e7702418'	System	22 Sep 2020 02:17:53
User entered 'Yes (Y)'	System	22 Sep 2020 02:17:53

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:17:45', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74de8830-83e3-4850-bd61-d4d4e7702418'	System	22 Sep 2020 02:17:53
User entered '98.2'	System	22 Sep 2020 02:17:53

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:17:47', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74de8830-83e3-4850-bd61-d4d4e7702418'	System	22 Sep 2020 02:17:53
User entered 'No (N)'	System	22 Sep 2020 02:17:53

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:17:49', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74de8830-83e3-4850-bd61-d4d4e7702418'	System	22 Sep 2020 02:17:53
User entered '21 Sep 2020 19:17'	System	22 Sep 2020 02:17:53

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 5'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:22', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5e66769b-122e-4524-97c3-bf4f5b452bc8'	System	23 Sep 2020 04:02:38
User entered 'Yes (Y)'	System	23 Sep 2020 04:02:38

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:25', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5e66769b-122e-4524-97c3-bf4f5b452bc8'	System	23 Sep 2020 04:02:38
User entered '97.6'	System	23 Sep 2020 04:02:38

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:27', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5e66769b-122e-4524-97c3-bf4f5b452bc8'	System	23 Sep 2020 04:02:38
User entered 'No (N)'	System	23 Sep 2020 04:02:38

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:30', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5e66769b-122e-4524-97c3-bf4f5b452bc8'	System	23 Sep 2020 04:02:38
User entered '22 Sep 2020 21:02'	System	23 Sep 2020 04:02:38

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 6'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:17:40', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5a524640-07c1-4454-be02-23f7efe5447'	System	24 Sep 2020 03:17:59
User entered 'Yes (Y)'	System	24 Sep 2020 03:17:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:17:43', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5a524640-07c1-4454-be02-23f7efe5447'	System	24 Sep 2020 03:17:59
User entered '97.8'	System	24 Sep 2020 03:17:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:17:49', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5a524640-07c1-4454-be02-23f7efe5447'	System	24 Sep 2020 03:17:59
User entered 'No (N)'	System	24 Sep 2020 03:17:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:17:55', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5a524640-07c1-4454-be02-23f7efe5447'	System	24 Sep 2020 03:17:59
User entered '23 Sep 2020 20:17'	System	24 Sep 2020 03:17:59

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 7'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:50', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b6efca32-4a6f-43b7-8c36-ff7cb7442e83'	System	25 Sep 2020 02:24:37
User entered 'Yes (Y)'	System	25 Sep 2020 02:24:37

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:55', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b6efea32-4a6f-43b7-8c36-ff7cb7442e83'	System	25 Sep 2020 02:24:37
User entered '98.0'	System	25 Sep 2020 02:24:37

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:24:01', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b6efea32-4a6f-43b7-8c36-ff7cb7442e83'	System	25 Sep 2020 02:24:37
User entered 'No (N)'	System	25 Sep 2020 02:24:37

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:24:27', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b6efea32-4a6f-43b7-8c36-ff7cb7442e83'	System	25 Sep 2020 02:24:37
User entered '24 Sep 2020 19:24'	System	25 Sep 2020 02:24:37

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:07', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '88178704-503b-4024-b28e-135fd6495494'	System	18 Sep 2020 22:15:27
User entered 'None (1)'	System	18 Sep 2020 22:15:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:13', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '88178704-503b-4024-b28e-135fd6495494'	System	18 Sep 2020 22:15:27
User entered 'No (N)'	System	18 Sep 2020 22:15:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:15', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '88178704-503b-4024-b28e-135fd6495494'	System	18 Sep 2020 22:15:27
User entered 'No (N)'	System	18 Sep 2020 22:15:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:19', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '88178704-503b-4024-b28e-135fd6495494'	System	18 Sep 2020 22:15:27
User entered 'None (1)'	System	18 Sep 2020 22:15:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:21', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '88178704-503b-4024-b28e-135fd6495494'	System	18 Sep 2020 22:15:27
User entered '18 Sep 2020 15:15'	System	18 Sep 2020 22:15:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 14:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 17:29'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:27:46', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6a90c810-4926-4699-9c46-0eb269f3d7ef'	System	19 Sep 2020 01:28:25
User entered 'None (1)'	System	19 Sep 2020 01:28:25

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:05', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6a90c810-4926-4699-9c46-0eb269f3d7ef'	System	19 Sep 2020 01:28:25
User entered 'No (N)'	System	19 Sep 2020 01:28:25

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:09', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6a90c810-4926-4699-9c46-0eb269f3d7ef'	System	19 Sep 2020 01:28:25
User entered 'No (N)'	System	19 Sep 2020 01:28:25

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:14', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6a90c810-4926-4699-9c46-0eb269f3d7ef'	System	19 Sep 2020 01:28:25
User entered 'None (1)'	System	19 Sep 2020 01:28:25

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:19', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6a90c810-4926-4699-9c46-0eb269f3d7ef' User entered '18 Sep 2020 18:28'	System	19 Sep 2020 01:28:25
	System	19 Sep 2020 01:28:25

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 18:24'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 2'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-19T12:35:30', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3a159ac2-9433-4c7a-9327-6722480a6751'	System	19 Sep 2020 19:35:44
User entered 'None (1)'	System	19 Sep 2020 19:35:44

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-19T12:35:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3a159ac2-9433-4c7a-9327-6722480a6751'	System	19 Sep 2020 19:35:44
User entered 'No (N)'	System	19 Sep 2020 19:35:44

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-19T12:35:35', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3a159ac2-9433-4c7a-9327-6722480a6751'	System	19 Sep 2020 19:35:44
User entered 'No (N)'	System	19 Sep 2020 19:35:44

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-19T12:35:38', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3a159ac2-9433-4c7a-9327-6722480a6751'	System	19 Sep 2020 19:35:44
User entered 'None (1)'	System	19 Sep 2020 19:35:44

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-19T12:35:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3a159ac2-9433-4c7a-9327-6722480a6751'	System	19 Sep 2020 19:35:44
User entered '19 Sep 2020 12:35'	System	19 Sep 2020 19:35:44

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 3'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:08:45', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a9d9869a-c579-4921-ad57-d6104fdf1d53'	System	21 Sep 2020 03:09:11
User entered 'None (1)'	System	21 Sep 2020 03:09:11

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:08:48', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a9d9869a-c579-4921-ad57-d6104fdf1d53'	System	21 Sep 2020 03:09:11
User entered 'No (N)'	System	21 Sep 2020 03:09:11

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:08:50', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a9d9869a-c579-4921-ad57-d6104fdf1d53'	System	21 Sep 2020 03:09:11
User entered 'No (N)'	System	21 Sep 2020 03:09:11

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:06', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a9d9869a-c579-4921-ad57-d6104fdf1d53'	System	21 Sep 2020 03:09:11
User entered 'None (1)'	System	21 Sep 2020 03:09:11

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:08', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a9d9869a-c579-4921-ad57-d6104fdf1d53'	System	21 Sep 2020 03:09:11
User entered '20 Sep 2020 20:09'	System	21 Sep 2020 03:09:11

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 4'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:12', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3398ee44-857a-462a-9cc5-1a2bdfc0612c'	System	22 Sep 2020 02:18:27
User entered 'None (1)'	System	22 Sep 2020 02:18:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:15', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3398ee44-857a-462a-9cc5-1a2bdfc0612c'	System	22 Sep 2020 02:18:27
User entered 'No (N)'	System	22 Sep 2020 02:18:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:17', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3398ee44-857a-462a-9cc5-1a2bdfc0612c'	System	22 Sep 2020 02:18:27
User entered 'No (N)'	System	22 Sep 2020 02:18:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:19', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3398ee44-857a-462a-9cc5-1a2bdfc0612c'	System	22 Sep 2020 02:18:27
User entered 'None (1)'	System	22 Sep 2020 02:18:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:23', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3398ee44-857a-462a-9cc5-1a2bdfc0612c'	System	22 Sep 2020 02:18:27
User entered '21 Sep 2020 19:18'	System	22 Sep 2020 02:18:27

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 5'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:01:59', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bb4728a6-7258-4495-b53d-8f7497a6b32f'	System	23 Sep 2020 04:02:24
User entered 'None (1)'	System	23 Sep 2020 04:02:24

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:06', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bb4728a6-7258-4495-b53d-8f7497a6b32f'	System	23 Sep 2020 04:02:24
User entered 'No (N)'	System	23 Sep 2020 04:02:24

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:08', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bb4728a6-7258-4495-b53d-8f7497a6b32f'	System	23 Sep 2020 04:02:24
User entered 'No (N)'	System	23 Sep 2020 04:02:24

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:11', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bb4728a6-7258-4495-b53d-8f7497a6b32f'	System	23 Sep 2020 04:02:24
User entered 'None (1)'	System	23 Sep 2020 04:02:24

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:17', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bb4728a6-7258-4495-b53d-8f7497a6b32f'	System	23 Sep 2020 04:02:24
User entered '22 Sep 2020 21:02'	System	23 Sep 2020 04:02:24

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 6'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ca6008ed-b16c-4bf6-8401-a183cc871c9b'	System	24 Sep 2020 03:18:33
User entered 'None (1)'	System	24 Sep 2020 03:18:33

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:20', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ca6008ed-b16c-4bf6-8401-a183cc871c9b'	System	24 Sep 2020 03:18:33
User entered 'No (N)'	System	24 Sep 2020 03:18:33

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:22', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ca6008ed-b16c-4bf6-8401-a183cc871c9b'	System	24 Sep 2020 03:18:33
User entered 'No (N)'	System	24 Sep 2020 03:18:33

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:24', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ca6008ed-b16c-4bf6-8401-a183cc871c9b'	System	24 Sep 2020 03:18:33
User entered 'None (1)'	System	24 Sep 2020 03:18:33

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:27', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ca6008ed-b16c-4bf6-8401-a183cc871c9b'	System	24 Sep 2020 03:18:33
User entered '23 Sep 2020 20:18'	System	24 Sep 2020 03:18:33

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 7'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:24:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '7b252efb-1100-4a07-99c2-a64b306d9f9d'	System	25 Sep 2020 02:24:46
User entered 'None (1)'	System	25 Sep 2020 02:24:46

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:24:35', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '7b252efb-1100-4a07-99c2-a64b306d9f9d'	System	25 Sep 2020 02:24:46
User entered 'No (N)'	System	25 Sep 2020 02:24:46

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:24:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '7b252efb-1100-4a07-99c2-a64b306d9f9d'	System	25 Sep 2020 02:24:46
User entered 'No (N)'	System	25 Sep 2020 02:24:46

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:24:39', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '7b252efb-1100-4a07-99c2-a64b306d9f9d'	System	25 Sep 2020 02:24:46
User entered 'None (1)'	System	25 Sep 2020 02:24:46

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:24:43', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '7b252efb-1100-4a07-99c2-a64b306d9f9d'	System	25 Sep 2020 02:24:46
User entered '24 Sep 2020 19:24'	System	25 Sep 2020 02:24:46

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:25', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bcf19a5f-2701-4be0-a596-554a52941a9a'	System	18 Sep 2020 22:15:44
User entered 'None (0)'	System	18 Sep 2020 22:15:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:26', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bcf19a5f-2701-4be0-a596-554a52941a9a'	System	18 Sep 2020 22:15:44
User entered 'None (0)'	System	18 Sep 2020 22:15:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:28', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bcf19a5f-2701-4be0-a596-554a52941a9a'	System	18 Sep 2020 22:15:44
User entered 'None (0)'	System	18 Sep 2020 22:15:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:30', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bcf19a5f-2701-4be0-a596-554a52941a9a'	System	18 Sep 2020 22:15:44
User entered 'None (0)'	System	18 Sep 2020 22:15:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:32', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bcf19a5f-2701-4be0-a596-554a52941a9a'	System	18 Sep 2020 22:15:44
User entered 'None (0)'	System	18 Sep 2020 22:15:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:34', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bcf19a5f-2701-4be0-a596-554a52941a9a'	System	18 Sep 2020 22:15:44
User entered 'None (0)'	System	18 Sep 2020 22:15:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bcf19a5f-2701-4be0-a596-554a52941a9a'	System	18 Sep 2020 22:15:44
User entered 'No (N)'	System	18 Sep 2020 22:15:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T15:15:39', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bcf19a5f-2701-4be0-a596-554a52941a9a'	System	18 Sep 2020 22:15:44
User entered '18 Sep 2020 15:15'	System	18 Sep 2020 22:15:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 14:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 17:29'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:22', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6763a764-56f9-48bd-9f42-7419a05a9ac9'	System	19 Sep 2020 01:28:40
User entered 'None (0)'	System	19 Sep 2020 01:28:40

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:24', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6763a764-56f9-48bd-9f42-7419a05a9ac9'	System	19 Sep 2020 01:28:40
User entered 'None (0)'	System	19 Sep 2020 01:28:40

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:26', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6763a764-56f9-48bd-9f42-7419a05a9ac9'	System	19 Sep 2020 01:28:40
User entered 'None (0)'	System	19 Sep 2020 01:28:40

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:27', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6763a764-56f9-48bd-9f42-7419a05a9ac9'	System	19 Sep 2020 01:28:40
User entered 'None (0)'	System	19 Sep 2020 01:28:40

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:29', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6763a764-56f9-48bd-9f42-7419a05a9ac9'	System	19 Sep 2020 01:28:40
User entered 'None (0)'	System	19 Sep 2020 01:28:40

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:30', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6763a764-56f9-48bd-9f42-7419a05a9ac9'	System	19 Sep 2020 01:28:40
User entered 'None (0)'	System	19 Sep 2020 01:28:40

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:32', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6763a764-56f9-48bd-9f42-7419a05a9ac9'	System	19 Sep 2020 01:28:40
User entered 'No (N)'	System	19 Sep 2020 01:28:40

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-18T18:28:34', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6763a764-56f9-48bd-9f42-7419a05a9ac9'	System	19 Sep 2020 01:28:40
User entered '18 Sep 2020 18:28'	System	19 Sep 2020 01:28:40

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Sep 2020 18:24'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 2'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:22:54', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '242cc397-54da-4fa1-93cb-59e5d70c38e8'	System	20 Sep 2020 08:23:12
User entered 'None (0)'	System	20 Sep 2020 08:23:12

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:22:56', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '242cc397-54da-4fa1-93cb-59e5d70c38e8'	System	20 Sep 2020 08:23:12
User entered 'None (0)'	System	20 Sep 2020 08:23:12

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:22:57', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '242cc397-54da-4fa1-93cb-59e5d70c38e8'	System	20 Sep 2020 08:23:12
User entered 'None (0)'	System	20 Sep 2020 08:23:12

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:22:59', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '242cc397-54da-4fa1-93cb-59e5d70c38e8'	System	20 Sep 2020 08:23:12
User entered 'None (0)'	System	20 Sep 2020 08:23:12

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:23:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '242cc397-54da-4fa1-93cb-59e5d70c38e8'	System	20 Sep 2020 08:23:12
User entered 'None (0)'	System	20 Sep 2020 08:23:12

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:23:02', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '242cc397-54da-4fa1-93cb-59e5d70c38e8'	System	20 Sep 2020 08:23:12
User entered 'None (0)'	System	20 Sep 2020 08:23:12

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:23:05', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '242cc397-54da-4fa1-93cb-59e5d70c38e8'	System	20 Sep 2020 08:23:12
User entered 'No (N)'	System	20 Sep 2020 08:23:12

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T01:23:09', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '242cc397-54da-4fa1-93cb-59e5d70c38e8'	System	20 Sep 2020 08:23:12
User entered '20 Sep 2020 01:23'	System	20 Sep 2020 08:23:12

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 3'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:11', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '86366956-b663-45a2-a156-a1b840e3ab57'	System	21 Sep 2020 03:09:29
User entered 'None (0)'	System	21 Sep 2020 03:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:12', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '86366956-b663-45a2-a156-a1b840e3ab57'	System	21 Sep 2020 03:09:29
User entered 'None (0)'	System	21 Sep 2020 03:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:13', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '86366956-b663-45a2-a156-a1b840e3ab57'	System	21 Sep 2020 03:09:29
User entered 'None (0)'	System	21 Sep 2020 03:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:15', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '86366956-b663-45a2-a156-a1b840e3ab57'	System	21 Sep 2020 03:09:29
User entered 'None (0)'	System	21 Sep 2020 03:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:16', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '86366956-b663-45a2-a156-a1b840e3ab57'	System	21 Sep 2020 03:09:29
User entered 'None (0)'	System	21 Sep 2020 03:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:17', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '86366956-b663-45a2-a156-a1b840e3ab57'	System	21 Sep 2020 03:09:29
User entered 'None (0)'	System	21 Sep 2020 03:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:20', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '86366956-b663-45a2-a156-a1b840e3ab57'	System	21 Sep 2020 03:09:29
User entered 'No (N)'	System	21 Sep 2020 03:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-20T20:09:23', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '86366956-b663-45a2-a156-a1b840e3ab57'	System	21 Sep 2020 03:09:29
User entered '20 Sep 2020 20:09'	System	21 Sep 2020 03:09:29

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 4'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:17:53', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8d239827-0843-43f0-8e1f-c5ce110e60dc'	System	22 Sep 2020 02:18:14
User entered 'None (0)'	System	22 Sep 2020 02:18:14

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:17:55', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8d239827-0843-43f0-8e1f-c5ce110e60dc'	System	22 Sep 2020 02:18:14
User entered 'None (0)'	System	22 Sep 2020 02:18:14

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:17:56', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8d239827-0843-43f0-8e1f-c5ce110e60dc'	System	22 Sep 2020 02:18:14
User entered 'None (0)'	System	22 Sep 2020 02:18:14

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8d239827-0843-43f0-8e1f-c5ce110e60dc'	System	22 Sep 2020 02:18:14
User entered 'None (0)'	System	22 Sep 2020 02:18:14

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:01', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8d239827-0843-43f0-8e1f-c5ce110e60dc'	System	22 Sep 2020 02:18:14
User entered 'None (0)'	System	22 Sep 2020 02:18:14

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:03', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8d239827-0843-43f0-8e1f-c5ce110e60dc'	System	22 Sep 2020 02:18:14
User entered 'None (0)'	System	22 Sep 2020 02:18:14

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:07', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8d239827-0843-43f0-8e1f-c5ce110e60dc'	System	22 Sep 2020 02:18:14
User entered 'No (N)'	System	22 Sep 2020 02:18:14

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-21T19:18:10', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8d239827-0843-43f0-8e1f-c5ce110e60dc'	System	22 Sep 2020 02:18:14
User entered '21 Sep 2020 19:18'	System	22 Sep 2020 02:18:14

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 5'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74ed6a4a-c871-4578-a203-834c6b23a628'	System	23 Sep 2020 04:02:53
User entered 'None (0)'	System	23 Sep 2020 04:02:53

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:34', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74ed6a4a-c871-4578-a203-834c6b23a628'	System	23 Sep 2020 04:02:53
User entered 'None (0)'	System	23 Sep 2020 04:02:53

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:35', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74ed6a4a-c871-4578-a203-834c6b23a628'	System	23 Sep 2020 04:02:53
User entered 'None (0)'	System	23 Sep 2020 04:02:53

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74ed6a4a-c871-4578-a203-834c6b23a628'	System	23 Sep 2020 04:02:53
User entered 'None (0)'	System	23 Sep 2020 04:02:53

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:38', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74ed6a4a-c871-4578-a203-834c6b23a628'	System	23 Sep 2020 04:02:53
User entered 'None (0)'	System	23 Sep 2020 04:02:53

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74ed6a4a-c871-4578-a203-834c6b23a628'	System	23 Sep 2020 04:02:53
User entered 'None (0)'	System	23 Sep 2020 04:02:53

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:46', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74ed6a4a-c871-4578-a203-834c6b23a628'	System	23 Sep 2020 04:02:53
User entered 'No (N)'	System	23 Sep 2020 04:02:53

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-22T21:02:48', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '74ed6a4a-c871-4578-a203-834c6b23a628'	System	23 Sep 2020 04:02:53
User entered '22 Sep 2020 21:02'	System	23 Sep 2020 04:02:53

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 6'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:30', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'e423c8e8-27d6-4e84-8026-04bd527219b9'	System	24 Sep 2020 03:18:45
User entered 'None (0)'	System	24 Sep 2020 03:18:45

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:32', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'e423c8e8-27d6-4e84-8026-04bd527219b9'	System	24 Sep 2020 03:18:45
User entered 'None (0)'	System	24 Sep 2020 03:18:45

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'e423c8e8-27d6-4e84-8026-04bd527219b9'	System	24 Sep 2020 03:18:45
User entered 'None (0)'	System	24 Sep 2020 03:18:45

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:34', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'e423c8e8-27d6-4e84-8026-04bd527219b9'	System	24 Sep 2020 03:18:45
User entered 'None (0)'	System	24 Sep 2020 03:18:45

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:36', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'e423c8e8-27d6-4e84-8026-04bd527219b9'	System	24 Sep 2020 03:18:45
User entered 'None (0)'	System	24 Sep 2020 03:18:45

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:38', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'e423c8e8-27d6-4e84-8026-04bd527219b9'	System	24 Sep 2020 03:18:45
User entered 'None (0)'	System	24 Sep 2020 03:18:45

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:40', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'e423c8e8-27d6-4e84-8026-04bd527219b9'	System	24 Sep 2020 03:18:45
User entered 'No (N)'	System	24 Sep 2020 03:18:45

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-23T20:18:42', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'e423c8e8-27d6-4e84-8026-04bd527219b9'	System	24 Sep 2020 03:18:45
User entered '23 Sep 2020 20:18'	System	24 Sep 2020 03:18:45

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 7'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:29', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cd5bca8c-fae8-4841-97d8-447fbb4fa1a7'	System	25 Sep 2020 02:23:44
User entered 'None (0)'	System	25 Sep 2020 02:23:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:30', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cd5bca8c-fae8-4841-97d8-447fbb4fa1a7'	System	25 Sep 2020 02:23:44
User entered 'None (0)'	System	25 Sep 2020 02:23:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:32', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cd5bca8c-fae8-4841-97d8-447fbb4fa1a7'	System	25 Sep 2020 02:23:44
User entered 'None (0)'	System	25 Sep 2020 02:23:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cd5bca8c-fae8-4841-97d8-447fbb4fa1a7'	System	25 Sep 2020 02:23:44
User entered 'None (0)'	System	25 Sep 2020 02:23:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:34', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cd5bca8c-fae8-4841-97d8-447fbb4fa1a7'	System	25 Sep 2020 02:23:44
User entered 'None (0)'	System	25 Sep 2020 02:23:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:35', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cd5bca8c-fae8-4841-97d8-447fbb4fa1a7'	System	25 Sep 2020 02:23:44
User entered 'None (0)'	System	25 Sep 2020 02:23:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cd5bca8c-fae8-4841-97d8-447fbb4fa1a7'	System	25 Sep 2020 02:23:44
User entered 'No (N)'	System	25 Sep 2020 02:23:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-09-24T19:23:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cd5bca8c-fae8-4841-97d8-447fbb4fa1a7'	System	25 Sep 2020 02:23:44
User entered '24 Sep 2020 19:23'	System	25 Sep 2020 02:23:44

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:48:06

US3582154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:41:27
User entered 'Yes (Y)'		28 Sep 2020 19:09:43

US3582154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:41:27
User entered '25 Sep 2020'		28 Sep 2020 19:09:43

US3582154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:41:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 19:09:43

US3582154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:41:27
User entered empty.		28 Sep 2020 19:09:43

US3582154

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:41:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Oct 2020 23:23:08

US3582154

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	03 Oct 2020 23:23:08

US3582154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Oct 2020 23:23:24

US3582154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:47
User entered '02 Oct 2020'	(b) (4), (b) (6)	03 Oct 2020 23:23:24

US3582154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Oct 2020 23:23:24

US3582154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:47
User entered empty.	(b) (4), (b) (6)	03 Oct 2020 23:23:24

US3582154

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:55
User entered 'Yes (Y)'	Stella Lee (b) (4)	12 Oct 2020 20:23:48

US3582154

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	12 Oct 2020 20:23:48

US3582154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:58
User entered 'Yes (Y)'	Stella Lee (b) (4)	12 Oct 2020 20:23:57

US3582154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:58
User entered '09 Oct 2020'	Stella Lee (b) (4)	12 Oct 2020 20:23:57

US3582154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:58
User entered 'Contact Made (CONTACT MADE)'	Stella Lee (b) (4)	12 Oct 2020 20:23:57

US3582154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:42:58
User entered empty.	Stella Lee (b) (4)	12 Oct 2020 20:23:57

US3582154

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:43:03
User entered 'Yes (Y)'	Melissa Scheer (b) (4) (b) (4)	14 Oct 2020 17:10:28

US3582154

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	14 Oct 2020 17:10:28

US3582154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:25:29

US3582154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:03
User entered '14 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 00:25:29

US3582154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[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 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:03
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 00:25:29

US3582154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'VISIT2'	System	15 Oct 2020 00:25:29

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '14 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '09:22'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '14 Oct 2020 09:22'	System	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '99.0' F	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered 'Other (Other)'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered 'temporal'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '74'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'bpm'	System	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '16'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'breaths/min'	System	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '112'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '69'	(b) (4), (b) (6)	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	15 Oct 2020 00:39:12

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered 'Yes (Y)'		15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '14 Oct 2020'		15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '10:26'	(b) (4), (b) (6)	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '14 Oct 2020 10:26'	System	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '99.8' F	(b) (4), (b) (6)	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered 'Other (Other)'	(b) (4), (b) (6)	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered 'temporal'	(b) (4), (b) (6)	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '70'		15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'bpm'	System	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '16'		15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'breaths/min'	System	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '112'		15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:44:08
User entered '71'	(b) (4), (b) (6)	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	15 Oct 2020 00:39:55

US3582154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4)	12 Nov 2020 21:44:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:40:27

US3582154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:44:52
User entered '14 Oct 2020'		15 Oct 2020 00:40:27

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4)	12 Nov 2020 21:45:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 01:08:48

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:45:08
User entered '14 Oct 2020'		15 Oct 2020 01:08:48

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:08
User entered 'Urine (URINE)'	(b) (4), (b) (6)	15 Oct 2020 01:08:48

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:08
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	15 Oct 2020 01:08:48

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:08
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 01:08:48

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:08
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:08:48

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:08
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:08:48

US3582154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered empty.	System	15 Oct 2020 01:08:48

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:17
User entered 'Yes (Y)'	Melissa Scheer (b) (4) (b) (4)	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:17
User entered empty.	Melissa Scheer (b) (4) (b) (4)	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

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 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:17
User entered empty.	Melissa Scheer (b) (4) (b) (4)	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:17
User entered '14 Oct 2020'	Melissa Scheer (b) (4) (b) (4)	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:17
User entered '09:55'	Melissa Scheer (b) (4) (b) (4)	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '14 Oct 2020 09:55'	System	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:17
User entered 'Left Arm (LEFT ARM)'	Melissa Scheer (b) (4) (b) (4)	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:17
User entered 'ONCE'	System	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 17:10:54

US3582154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 01:09:03

US3582154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:33
User entered '14 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 01:09:03

US3582154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:33
User entered '09:41'	(b) (4), (b) (6)	15 Oct 2020 01:09:03

US3582154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '14 Oct 2020 09:41'	System	15 Oct 2020 01:09:03

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:01:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:38
User entered '14 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:38
User entered '09:45'	(b) (4), (b) (6)	15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '14 Oct 2020 09:45'	System	15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:01:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:38
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:45:38
User entered empty.		15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered empty.	System	15 Oct 2020 01:09:21

US3582154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:45:45
User entered 'Yes (Y)'	Stella Lee (b) (4)	23 Oct 2020 20:28:15

US3582154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	23 Oct 2020 20:28:15

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:06', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '12c74ab9-2d26-40ab-b51f-a27f33aafc33'	System	14 Oct 2020 17:30:25
User entered 'Yes (Y)'	System	14 Oct 2020 17:30:25

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:11', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '12c74ab9-2d26-40ab-b51f-a27f33aafc33'	System	14 Oct 2020 17:30:25
User entered '99.8'	System	14 Oct 2020 17:30:25

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:16', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '12c74ab9-2d26-40ab-b51f-a27f33aafc33'	System	14 Oct 2020 17:30:25
User entered 'No (N)'	System	14 Oct 2020 17:30:25

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:23', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '12c74ab9-2d26-40ab-b51f-a27f33aafc33'	System	14 Oct 2020 17:30:25
User entered '14 Oct 2020 10:30'	System	14 Oct 2020 17:30:25

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 10:15'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 12:45'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:34:27', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b111ce73-738c-4376-a301-c1314049bcc0'	System	15 Oct 2020 01:34:40
User entered 'Yes (Y)'	System	15 Oct 2020 01:34:40

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:34:30', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b111ce73-738c-4376-a301-c1314049bcc0'	System	15 Oct 2020 01:34:40
User entered '98.1'	System	15 Oct 2020 01:34:40

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:34:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b111ce73-738c-4376-a301-c1314049bcc0'	System	15 Oct 2020 01:34:40
User entered 'No (N)'	System	15 Oct 2020 01:34:40

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:34:36', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b111ce73-738c-4376-a301-c1314049bcc0'	System	15 Oct 2020 01:34:40
User entered '14 Oct 2020 18:34'	System	15 Oct 2020 01:34:40

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 13:40'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 2'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '0a416780-4700-48e6-87a8-925f3ac59195'	System	16 Oct 2020 13:14:21
User entered 'Yes (Y)'	System	16 Oct 2020 13:14:21

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:05', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '0a416780-4700-48e6-87a8-925f3ac59195'	System	16 Oct 2020 13:14:21
User entered '97.6'	System	16 Oct 2020 13:14:21

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:09', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '0a416780-4700-48e6-87a8-925f3ac59195'	System	16 Oct 2020 13:14:21
User entered 'Yes (Y)'	System	16 Oct 2020 13:14:21

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient had headache, Took ibuprofen and it resolved in a few hours.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 05:07:52
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	16 Oct 2020 13:14:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:13', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '0a416780-4700-48e6-87a8-925f3ac59195'	System	16 Oct 2020 13:14:21
User entered '1'	System	16 Oct 2020 13:14:21

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:13', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '0a416780-4700-48e6-87a8-925f3ac59195'	System	16 Oct 2020 13:14:21
User entered '0'	System	16 Oct 2020 13:14:21

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:15', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '0a416780-4700-48e6-87a8-925f3ac59195'	System	16 Oct 2020 13:14:21
User entered '16 Oct 2020 06:14'	System	16 Oct 2020 13:14:21

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 3'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 4'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:11:06', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5a7f0515-515a-4d6d-8548-55fbe259b3c8'	System	18 Oct 2020 17:11:13
User entered 'No (N)'	System	18 Oct 2020 17:11:13

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:11:08', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5a7f0515-515a-4d6d-8548-55fbe259b3c8'	System	18 Oct 2020 17:11:13
User entered 'No (N)'	System	18 Oct 2020 17:11:13

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:11:10', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5a7f0515-515a-4d6d-8548-55fbe259b3c8'	System	18 Oct 2020 17:11:13
User entered '18 Oct 2020 10:11'	System	18 Oct 2020 17:11:13

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 5'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '68a42caa-bd1c-493b-996e-9d6d917bcfa3'	System	19 Oct 2020 03:21:11
User entered 'Yes (Y)'	System	19 Oct 2020 03:21:11

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:04', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '68a42caa-bd1c-493b-996e-9d6d917bcfa3'	System	19 Oct 2020 03:21:11
User entered '98.2'	System	19 Oct 2020 03:21:11

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:06', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '68a42caa-bd1c-493b-996e-9d6d917bcfa3'	System	19 Oct 2020 03:21:11
User entered 'No (N)'	System	19 Oct 2020 03:21:11

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:09', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '68a42caa-bd1c-493b-996e-9d6d917bcfa3'	System	19 Oct 2020 03:21:11
User entered '18 Oct 2020 20:21'	System	19 Oct 2020 03:21:11

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 6'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:21', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9acdbb29-8766-4809-b735-e8bacba3fad4'	System	20 Oct 2020 12:34:40
User entered 'Yes (Y)'	System	20 Oct 2020 12:34:40

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:31', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9acdbb29-8766-4809-b735-e8bacba3fad4'	System	20 Oct 2020 12:34:40
User entered '98.6'	System	20 Oct 2020 12:34:40

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9acdbb29-8766-4809-b735-e8bacba3fad4'	System	20 Oct 2020 12:34:40
User entered 'No (N)'	System	20 Oct 2020 12:34:40

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9acdbb29-8766-4809-b735-e8bacba3fad4'	System	20 Oct 2020 12:34:40
User entered '20 Oct 2020 05:34'	System	20 Oct 2020 12:34:40

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 7'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:07:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a35858cb-f2bb-420b-9f8c-c0a078cb81f9'	System	21 Oct 2020 04:07:49
User entered 'Yes (Y)'	System	21 Oct 2020 04:07:49

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:07:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a35858cb-f2bb-420b-9f8c-c0a078cb81f9'	System	21 Oct 2020 04:07:49
User entered '96.9'	System	21 Oct 2020 04:07:49

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:07:40', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a35858cb-f2bb-420b-9f8c-c0a078cb81f9'	System	21 Oct 2020 04:07:49
User entered 'No (N)'	System	21 Oct 2020 04:07:49

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:07:46', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'a35858cb-f2bb-420b-9f8c-c0a078cb81f9'	System	21 Oct 2020 04:07:49
User entered '20 Oct 2020 21:07'	System	21 Oct 2020 04:07:49

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb46185b-af13-43fa-a183-e817acb5c76b'	System	14 Oct 2020 17:30:57
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 17:30:57

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:39', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb46185b-af13-43fa-a183-e817acb5c76b'	System	14 Oct 2020 17:30:57
User entered 'No (N)'	System	14 Oct 2020 17:30:57

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:44', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb46185b-af13-43fa-a183-e817acb5c76b'	System	14 Oct 2020 17:30:57
User entered 'No (N)'	System	14 Oct 2020 17:30:57

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:52', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb46185b-af13-43fa-a183-e817acb5c76b'	System	14 Oct 2020 17:30:57
User entered 'None (1)'	System	14 Oct 2020 17:30:57

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:55', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb46185b-af13-43fa-a183-e817acb5c76b'	System	14 Oct 2020 17:30:57
User entered '14 Oct 2020 10:30'	System	14 Oct 2020 17:30:57

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 10:15'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 12:45'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:34:49', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8a81bf57-42a0-4483-80d9-7d916e5b797e'	System	15 Oct 2020 01:35:10
User entered 'None (1)'	System	15 Oct 2020 01:35:10

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:34:51', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8a81bf57-42a0-4483-80d9-7d916e5b797e'	System	15 Oct 2020 01:35:10
User entered 'No (N)'	System	15 Oct 2020 01:35:10

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:34:57', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8a81bf57-42a0-4483-80d9-7d916e5b797e'	System	15 Oct 2020 01:35:10
User entered 'No (N)'	System	15 Oct 2020 01:35:10

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:34:59', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8a81bf57-42a0-4483-80d9-7d916e5b797e'	System	15 Oct 2020 01:35:10
User entered 'None (1)'	System	15 Oct 2020 01:35:10

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:06', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8a81bf57-42a0-4483-80d9-7d916e5b797e' User entered '14 Oct 2020 18:35'	System	15 Oct 2020 01:35:10
	System	15 Oct 2020 01:35:10

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 13:40'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 2'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:19', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ab97e942-dc78-4e10-9868-e9b1b6599c4e'	System	16 Oct 2020 13:14:36
User entered 'None (1)'	System	16 Oct 2020 13:14:36

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:21', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ab97e942-dc78-4e10-9868-e9b1b6599c4e'	System	16 Oct 2020 13:14:36
User entered 'No (N)'	System	16 Oct 2020 13:14:36

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:23', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ab97e942-dc78-4e10-9868-e9b1b6599c4e'	System	16 Oct 2020 13:14:36
User entered 'No (N)'	System	16 Oct 2020 13:14:36

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:25', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ab97e942-dc78-4e10-9868-e9b1b6599c4e'	System	16 Oct 2020 13:14:36
User entered 'None (1)'	System	16 Oct 2020 13:14:36

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:14:31', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ab97e942-dc78-4e10-9868-e9b1b6599c4e' User entered '16 Oct 2020 06:14'	System	16 Oct 2020 13:14:36
	System	16 Oct 2020 13:14:36

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 3'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 4'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:51', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb991213-3d11-457f-b201-7bfdda86258a'	System	18 Oct 2020 17:10:58
User entered 'None (1)'	System	18 Oct 2020 17:10:58

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:52', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb991213-3d11-457f-b201-7bfdda86258a'	System	18 Oct 2020 17:10:58
User entered 'No (N)'	System	18 Oct 2020 17:10:58

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:54', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb991213-3d11-457f-b201-7bfd86258a'	System	18 Oct 2020 17:10:58
User entered 'No (N)'	System	18 Oct 2020 17:10:58

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:55', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb991213-3d11-457f-b201-7bfdda86258a'	System	18 Oct 2020 17:10:58
User entered 'None (1)'	System	18 Oct 2020 17:10:58

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:57', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'cb991213-3d11-457f-b201-7bfdda86258a'	System	18 Oct 2020 17:10:58
User entered '18 Oct 2020 10:10'	System	18 Oct 2020 17:10:58

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 5'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:13', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8817f593-5ece-4fe2-af2f-0556ac24cc33'	System	19 Oct 2020 03:21:26
User entered 'None (1)'	System	19 Oct 2020 03:21:26

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:16', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8817f593-5ece-4fe2-af2f-0556ac24cc33'	System	19 Oct 2020 03:21:26
User entered 'No (N)'	System	19 Oct 2020 03:21:26

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:18', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8817f593-5ece-4fe2-af2f-0556ac24cc33'	System	19 Oct 2020 03:21:26
User entered 'No (N)'	System	19 Oct 2020 03:21:26

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:20', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8817f593-5ece-4fe2-af2f-0556ac24cc33'	System	19 Oct 2020 03:21:26
User entered 'None (1)'	System	19 Oct 2020 03:21:26

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:21:23', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8817f593-5ece-4fe2-af2f-0556ac24cc33'	System	19 Oct 2020 03:21:26
User entered '18 Oct 2020 20:21'	System	19 Oct 2020 03:21:26

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 6'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:43', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '41330c78-fdae-4828-91ee-26e9611bf8cc'	System	20 Oct 2020 12:34:54
User entered 'None (1)'	System	20 Oct 2020 12:34:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:46', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '41330c78-fdae-4828-91ee-26e9611bf8cc'	System	20 Oct 2020 12:34:54
User entered 'No (N)'	System	20 Oct 2020 12:34:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:48', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '41330c78-fdae-4828-91ee-26e9611bf8cc'	System	20 Oct 2020 12:34:54
User entered 'No (N)'	System	20 Oct 2020 12:34:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:50', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '41330c78-fdae-4828-91ee-26e9611bf8cc'	System	20 Oct 2020 12:34:54
User entered 'None (1)'	System	20 Oct 2020 12:34:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:53', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '41330c78-fdae-4828-91ee-26e9611bf8cc' User entered '20 Oct 2020 05:34'	System	20 Oct 2020 12:34:54
	System	20 Oct 2020 12:34:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 7'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:09', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3c9cf2cc-baeb-4033-8699-472106034766'	System	21 Oct 2020 04:14:20
User entered 'None (1)'	System	21 Oct 2020 04:14:20

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:11', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3c9cf2cc-baeb-4033-8699-472106034766'	System	21 Oct 2020 04:14:20
User entered 'No (N)'	System	21 Oct 2020 04:14:20

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:12', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3c9cf2cc-baeb-4033-8699-472106034766'	System	21 Oct 2020 04:14:20
User entered 'No (N)'	System	21 Oct 2020 04:14:20

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:15', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3c9cf2cc-baeb-4033-8699-472106034766'	System	21 Oct 2020 04:14:20
User entered 'None (1)'	System	21 Oct 2020 04:14:20

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:17', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3c9cf2cc-baeb-4033-8699-472106034766'	System	21 Oct 2020 04:14:20
User entered '20 Oct 2020 21:14'	System	21 Oct 2020 04:14:20

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:30:59', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fa4a182b-5d90-4fc9-bb21-17f291ab0d52'	System	14 Oct 2020 17:31:19
User entered 'None (0)'	System	14 Oct 2020 17:31:19

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:31:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fa4a182b-5d90-4fc9-bb21-17f291ab0d52'	System	14 Oct 2020 17:31:19
User entered 'None (0)'	System	14 Oct 2020 17:31:19

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:31:02', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fa4a182b-5d90-4fc9-bb21-17f291ab0d52'	System	14 Oct 2020 17:31:19
User entered 'None (0)'	System	14 Oct 2020 17:31:19

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:31:04', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fa4a182b-5d90-4fc9-bb21-17f291ab0d52'	System	14 Oct 2020 17:31:19
User entered 'None (0)'	System	14 Oct 2020 17:31:19

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:31:05', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fa4a182b-5d90-4fc9-bb21-17f291ab0d52'	System	14 Oct 2020 17:31:19
User entered 'None (0)'	System	14 Oct 2020 17:31:19

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:31:06', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fa4a182b-5d90-4fc9-bb21-17f291ab0d52'	System	14 Oct 2020 17:31:19
User entered 'None (0)'	System	14 Oct 2020 17:31:19

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:31:13', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fa4a182b-5d90-4fc9-bb21-17f291ab0d52'	System	14 Oct 2020 17:31:19
User entered 'No (N)'	System	14 Oct 2020 17:31:19

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T10:31:16', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fa4a182b-5d90-4fc9-bb21-17f291ab0d52'	System	14 Oct 2020 17:31:19
User entered '14 Oct 2020 10:31'	System	14 Oct 2020 17:31:19

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 10:15'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 12:45'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:10', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1619dab1-ebe0-4d72-b5b8-eb2327318309'	System	15 Oct 2020 01:35:36
User entered 'None (0)'	System	15 Oct 2020 01:35:36

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:18', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1619dab1-ebe0-4d72-b5b8-eb2327318309'	System	15 Oct 2020 01:35:36
User entered 'Significant; prevents daily activity (3)'	System	15 Oct 2020 01:35:36

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:20', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1619dab1-ebe0-4d72-b5b8-eb2327318309'	System	15 Oct 2020 01:35:36
User entered 'None (0)'	System	15 Oct 2020 01:35:36

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:23', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1619dab1-ebe0-4d72-b5b8-eb2327318309'	System	15 Oct 2020 01:35:36
User entered 'None (0)'	System	15 Oct 2020 01:35:36

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:25', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1619dab1-ebe0-4d72-b5b8-eb2327318309'	System	15 Oct 2020 01:35:36
User entered 'None (0)'	System	15 Oct 2020 01:35:36

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:26', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1619dab1-ebe0-4d72-b5b8-eb2327318309'	System	15 Oct 2020 01:35:36
User entered 'None (0)'	System	15 Oct 2020 01:35:36

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:29', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1619dab1-ebe0-4d72-b5b8-eb2327318309'	System	15 Oct 2020 01:35:36
User entered 'No (N)'	System	15 Oct 2020 01:35:36

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-14T18:35:31', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1619dab1-ebe0-4d72-b5b8-eb2327318309'	System	15 Oct 2020 01:35:36
User entered '14 Oct 2020 18:35'	System	15 Oct 2020 01:35:36

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '14 Oct 2020 13:40'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 2'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:13:36', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '42cbcc5d-afe3-4a28-aabf-e024207d78f1'	System	16 Oct 2020 13:13:59
User entered 'None (0)'	System	16 Oct 2020 13:13:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:13:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '42cbcc5d-afe3-4a28-aabf-e024207d78f1'	System	16 Oct 2020 13:13:59
User entered 'No interference with activity (1)'	System	16 Oct 2020 13:13:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:13:43', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '42cbcc5d-afe3-4a28-aabf-e024207d78f1'	System	16 Oct 2020 13:13:59
User entered 'None (0)'	System	16 Oct 2020 13:13:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:13:45', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '42cbcc5d-afe3-4a28-aabf-e024207d78f1'	System	16 Oct 2020 13:13:59
User entered 'None (0)'	System	16 Oct 2020 13:13:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:13:47', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '42cbcc5d-afe3-4a28-aabf-e024207d78f1'	System	16 Oct 2020 13:13:59
User entered 'None (0)'	System	16 Oct 2020 13:13:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:13:49', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '42cbcc5d-afe3-4a28-aabf-e024207d78f1'	System	16 Oct 2020 13:13:59
User entered 'None (0)'	System	16 Oct 2020 13:13:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:13:53', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '42cbcc5d-afe3-4a28-aabf-e024207d78f1'	System	16 Oct 2020 13:13:59
User entered 'No (N)'	System	16 Oct 2020 13:13:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-16T06:13:55', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '42cbcc5d-afe3-4a28-aabf-e024207d78f1'	System	16 Oct 2020 13:13:59
User entered '16 Oct 2020 06:13'	System	16 Oct 2020 13:13:59

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 3'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 4'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '37019a7d-aa3a-488d-805a-d5cb2f66ac79'	System	18 Oct 2020 17:10:44
User entered 'None (0)'	System	18 Oct 2020 17:10:44

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:34', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '37019a7d-aa3a-488d-805a-d5cb2f66ac79'	System	18 Oct 2020 17:10:44
User entered 'None (0)'	System	18 Oct 2020 17:10:44

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:35', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '37019a7d-aa3a-488d-805a-d5cb2f66ac79'	System	18 Oct 2020 17:10:44
User entered 'None (0)'	System	18 Oct 2020 17:10:44

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:36', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '37019a7d-aa3a-488d-805a-d5cb2f66ac79'	System	18 Oct 2020 17:10:44
User entered 'None (0)'	System	18 Oct 2020 17:10:44

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '37019a7d-aa3a-488d-805a-d5cb2f66ac79'	System	18 Oct 2020 17:10:44
User entered 'None (0)'	System	18 Oct 2020 17:10:44

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:38', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '37019a7d-aa3a-488d-805a-d5cb2f66ac79'	System	18 Oct 2020 17:10:44
User entered 'None (0)'	System	18 Oct 2020 17:10:44

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:40', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '37019a7d-aa3a-488d-805a-d5cb2f66ac79'	System	18 Oct 2020 17:10:44
User entered 'No (N)'	System	18 Oct 2020 17:10:44

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T10:10:43', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '37019a7d-aa3a-488d-805a-d5cb2f66ac79'	System	18 Oct 2020 17:10:44
User entered '18 Oct 2020 10:10'	System	18 Oct 2020 17:10:44

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 5'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:20:29', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '29d74ecc-8a51-431a-b432-b6f6f40f8433'	System	19 Oct 2020 03:20:42
User entered 'None (0)'	System	19 Oct 2020 03:20:42

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:20:31', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '29d74ecc-8a51-431a-b432-b6f6f40f8433'	System	19 Oct 2020 03:20:42
User entered 'None (0)'	System	19 Oct 2020 03:20:42

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:20:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '29d74ecc-8a51-431a-b432-b6f6f40f8433'	System	19 Oct 2020 03:20:42
User entered 'None (0)'	System	19 Oct 2020 03:20:42

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:20:34', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '29d74ecc-8a51-431a-b432-b6f6f40f8433'	System	19 Oct 2020 03:20:42
User entered 'None (0)'	System	19 Oct 2020 03:20:42

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:20:36', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '29d74ecc-8a51-431a-b432-b6f6f40f8433'	System	19 Oct 2020 03:20:42
User entered 'None (0)'	System	19 Oct 2020 03:20:42

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:20:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '29d74ecc-8a51-431a-b432-b6f6f40f8433'	System	19 Oct 2020 03:20:42
User entered 'None (0)'	System	19 Oct 2020 03:20:42

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:20:39', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '29d74ecd-8a51-431a-b432-b6f6f40f8433'	System	19 Oct 2020 03:20:42
User entered 'No (N)'	System	19 Oct 2020 03:20:42

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-18T20:20:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '29d74ecc-8a51-431a-b432-b6f6f40f8433'	System	19 Oct 2020 03:20:42
User entered '18 Oct 2020 20:20'	System	19 Oct 2020 03:20:42

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 6'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:34:58', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '78d45903-314e-4e25-8fde-a3958790a048'	System	20 Oct 2020 12:35:17
User entered 'None (0)'	System	20 Oct 2020 12:35:17

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:35:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '78d45903-314e-4e25-8fde-a3958790a048'	System	20 Oct 2020 12:35:17
User entered 'None (0)'	System	20 Oct 2020 12:35:17

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:35:03', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '78d45903-314e-4e25-8fde-a3958790a048'	System	20 Oct 2020 12:35:17
User entered 'None (0)'	System	20 Oct 2020 12:35:17

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:35:04', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '78d45903-314e-4e25-8fde-a3958790a048'	System	20 Oct 2020 12:35:17
User entered 'None (0)'	System	20 Oct 2020 12:35:17

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:35:08', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '78d45903-314e-4e25-8fde-a3958790a048'	System	20 Oct 2020 12:35:17
User entered 'None (0)'	System	20 Oct 2020 12:35:17

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:35:09', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '78d45903-314e-4e25-8fde-a3958790a048'	System	20 Oct 2020 12:35:17
User entered 'None (0)'	System	20 Oct 2020 12:35:17

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:35:13', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '78d45903-314e-4e25-8fde-a3958790a048'	System	20 Oct 2020 12:35:17
User entered 'No (N)'	System	20 Oct 2020 12:35:17

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T05:35:16', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '78d45903-314e-4e25-8fde-a3958790a048'	System	20 Oct 2020 12:35:17
User entered '20 Oct 2020 05:35'	System	20 Oct 2020 12:35:17

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
Data entry locked.	System	14 Oct 2020 17:10:54
User entered 'Day 7'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:13:57', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b3fa44c9-79f3-486b-84fa-89cb005c49cd'	System	21 Oct 2020 04:14:08
User entered 'None (0)'	System	21 Oct 2020 04:14:08

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:13:58', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b3fa44c9-79f3-486b-84fa-89cb005c49cd'	System	21 Oct 2020 04:14:08
User entered 'None (0)'	System	21 Oct 2020 04:14:08

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:13:59', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b3fa44c9-79f3-486b-84fa-89cb005c49cd'	System	21 Oct 2020 04:14:08
User entered 'None (0)'	System	21 Oct 2020 04:14:08

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b3fa44c9-79f3-486b-84fa-89cb005c49cd'	System	21 Oct 2020 04:14:08
User entered 'None (0)'	System	21 Oct 2020 04:14:08

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:01', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b3fa44c9-79f3-486b-84fa-89cb005c49cd'	System	21 Oct 2020 04:14:08
User entered 'None (0)'	System	21 Oct 2020 04:14:08

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:03', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b3fa44c9-79f3-486b-84fa-89cb005c49cd'	System	21 Oct 2020 04:14:08
User entered 'None (0)'	System	21 Oct 2020 04:14:08

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

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 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:05', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b3fa44c9-79f3-486b-84fa-89cb005c49cd'	System	21 Oct 2020 04:14:08
User entered 'No (N)'	System	21 Oct 2020 04:14:08

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-10-20T21:14:06', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'b3fa44c9-79f3-486b-84fa-89cb005c49cd' User entered '20 Oct 2020 21:14'	System	21 Oct 2020 04:14:08
	System	21 Oct 2020 04:14:08

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 17:10:54

US3582154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:01:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:34:53
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 17:10:54

US3582154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:48:42
User entered 'Yes (Y)'	Stella Lee (b) (4)	23 Oct 2020 20:28:24

US3582154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:48:42
User entered '22 Oct 2020'	Stella Lee (b) (4)	23 Oct 2020 20:28:24

US3582154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:48:42
User entered 'Contact Made (CONTACT MADE)'	Stella Lee (b) (4)	23 Oct 2020 20:28:24

US3582154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:48:42
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:28:24

US3582154

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:49:11
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:35:06

US3582154

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	30 Oct 2020 00:35:06

US3582154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:49:15
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:35:21

US3582154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:49:15
User entered '29 Oct 2020'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:35:21

US3582154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:49:15
User entered 'Contact Made (CONTACT MADE)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:35:21

US3582154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:49:15
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:35:21

US3582154

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:50:21
User entered 'Yes (Y)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:34:46

US3582154

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	09 Nov 2020 21:34:46

US3582154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:51:50
User entered 'Yes (Y)'	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:34:55

US3582154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:51:50
User entered '6 Nov 2020'	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:34:55

US3582154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:51:50
User entered 'Contact Made (CONTACT MADE)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:34:55

US3582154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:51:50
User entered empty.	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:34:55

US3582154

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:50:37
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:01

US3582154

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	12 Nov 2020 01:19:01

US3582154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:51:24
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:17

US3582154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:51:24
User entered '11 Nov 2020'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:17

US3582154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[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 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:51:24
User entered 'Clinic (Clinic)'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:17

US3582154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'VISIT3'	System	12 Nov 2020 01:19:17

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered '11 Nov 2020'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered '08:07'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '11 Nov 2020 08:07'	System	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered '98.9' F	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered 'Other (Other)'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered 'Temporal'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered '83'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'bpm'	System	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered '14'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'breaths/min'	System	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered '126'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:41
User entered '67'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'mmHg'	System	12 Nov 2020 01:19:41

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42

US3582154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42

US3582154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:59
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:59

US3582154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:52:59
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:59

US3582154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:53:43
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:52

US3582154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:53:43
User entered '11 Nov 2020'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:52

US3582154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:53:43
User entered '08:20'	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:19:52

US3582154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered '11 Nov 2020 08:20'	System	12 Nov 2020 01:19:52

US3582154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
DataPoint Verified.	(b) (4)	18 Feb 2021 20:53:46
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:13
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	11 Dec 2020 01:02:31

US3582154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	11 Dec 2020 01:02:31

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38
Data entry locked.	System	18 Sep 2020 21:48:06
User entered 'Day 64'	System	18 Sep 2020 21:48:06

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38
Data entry locked.	System	18 Sep 2020 21:48:06
User entered '18 Nov 2020 00:01'	System	18 Sep 2020 21:48:06

US3582154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:38
Data entry locked.	System	18 Sep 2020 21:48:06
User entered '22 Nov 2020 23:59'	System	18 Sep 2020 21:48:06

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2020-12-03T10:55:12', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '69d0189e-b925-489a-bfe0-db5af8064d04'	System	03 Dec 2020 18:55:22
User entered 'No (N)'	System	03 Dec 2020 18:55:22

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2020-12-03T10:55:16', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '69d0189e-b925-489a-bfe0-db5af8064d04'	System	03 Dec 2020 18:55:22
User entered 'No (N)'	System	03 Dec 2020 18:55:22

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-12-03T10:55:19', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '69d0189e-b925-489a-bfe0-db5af8064d04'	System	03 Dec 2020 18:55:22
User entered '03 Dec 2020 10:55:19'	System	03 Dec 2020 18:55:22

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2020-12-06T07:39:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ea138449-af57-4e49-b3ea-a9510e2199c9'	System	06 Dec 2020 15:40:05
User entered 'Yes (Y)'	System	06 Dec 2020 15:40:05

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2020-12-06T07:39:46', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ea138449-af57-4e49-b3ea-a9510e2199c9'	System	06 Dec 2020 15:40:05
User entered 'No (N)'	System	06 Dec 2020 15:40:05

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 (471e01af26465b51)', Time: '2020-12-06T07:39:51', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ea138449-af57-4e49-b3ea-a9510e2199c9'	System	06 Dec 2020 15:40:05
User entered 'No (N)'	System	06 Dec 2020 15:40:05

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 (471e01af26465b51)', Time: '2020-12-06T07:39:57', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ea138449-af57-4e49-b3ea-a9510e2199c9'	System	06 Dec 2020 15:40:05
User entered 'No (N)'	System	06 Dec 2020 15:40:05

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-12-06T07:40:01', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ea138449-af57-4e49-b3ea-a9510e2199c9'	System	06 Dec 2020 15:40:05
User entered '06 Dec 2020 07:40:01'	System	06 Dec 2020 15:40:05

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2020-12-13T09:00:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9155932d-1e3b-423e-aedc-bbb4b645469a'	System	13 Dec 2020 17:00:57
User entered 'Yes (Y)'	System	13 Dec 2020 17:00:57

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2020-12-13T09:00:44', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9155932d-1e3b-423e-aedc-bbb4b645469a'	System	13 Dec 2020 17:00:57
User entered 'No (N)'	System	13 Dec 2020 17:00:57

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 (471e01af26465b51)', Time: '2020-12-13T09:00:46', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9155932d-1e3b-423e-aedc-bbb4b645469a'	System	13 Dec 2020 17:00:57
User entered 'No (N)'	System	13 Dec 2020 17:00:57

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 (471e01af26465b51)', Time: '2020-12-13T09:00:48', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9155932d-1e3b-423e-aedc-bbb4b645469a'	System	13 Dec 2020 17:00:57
User entered 'No (N)'	System	13 Dec 2020 17:00:57

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-12-13T09:00:52', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '9155932d-1e3b-423e-aedc-bbb4b645469a' User entered '13 Dec 2020 09:00:52'	System	13 Dec 2020 17:00:57
	System	13 Dec 2020 17:00:57

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2020-12-28T15:25:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bf378149-9021-4848-b6b3-6fef65af6ae1'	System	28 Dec 2020 23:25:47
User entered 'No (N)'	System	28 Dec 2020 23:25:47

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2020-12-28T15:25:39', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bf378149-9021-4848-b6b3-6fef65af6ae1'	System	28 Dec 2020 23:25:47
User entered 'No (N)'	System	28 Dec 2020 23:25:47

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2020-12-28T15:25:42', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'bf378149-9021-4848-b6b3-6fef65af6ae1'	System	28 Dec 2020 23:25:47
User entered '28 Dec 2020 15:25:42'	System	28 Dec 2020 23:25:47

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-01-03T08:16:10', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5330c8ca-c3ea-4329-8471-c5ccc24caf7e'	System	03 Jan 2021 16:16:19
User entered 'No (N)'	System	03 Jan 2021 16:16:19

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-01-03T08:16:14', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5330c8ca-c3ea-4329-8471-c5ccc24caf7e'	System	03 Jan 2021 16:16:19
User entered 'No (N)'	System	03 Jan 2021 16:16:19

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-01-03T08:16:16', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '5330c8ca-c3ea-4329-8471-c5ccc24caf7e'	System	03 Jan 2021 16:16:19
User entered '03 Jan 2021 08:16:16'	System	03 Jan 2021 16:16:19

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-01-12T12:08:49', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'd522a1dd-19c5-49e6-ba80-05d997fe0c7d'	System	12 Jan 2021 20:08:56
User entered 'No (N)'	System	12 Jan 2021 20:08:56

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-01-12T12:08:51', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'd522a1dd-19c5-49e6-ba80-05d997fe0c7d'	System	12 Jan 2021 20:08:56
User entered 'No (N)'	System	12 Jan 2021 20:08:56

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-01-12T12:08:54', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'd522a1dd-19c5-49e6-ba80-05d997fe0c7d'	System	12 Jan 2021 20:08:56
User entered '12 Jan 2021 12:08:54'	System	12 Jan 2021 20:08:56

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-01-17T07:58:28', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fd465e55-3443-47ae-a14b-496acf6fb9cd'	System	17 Jan 2021 15:58:36
User entered 'No (N)'	System	17 Jan 2021 15:58:36

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-01-17T07:58:31', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fd465e55-3443-47ae-a14b-496acf6fb9cd'	System	17 Jan 2021 15:58:36
User entered 'No (N)'	System	17 Jan 2021 15:58:36

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-01-17T07:58:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fd465e55-3443-47ae-a14b-496acf6fb9cd'	System	17 Jan 2021 15:58:36
User entered '17 Jan 2021 07:58:33'	System	17 Jan 2021 15:58:36

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-01-24T06:08:25', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3caae334-eea3-4b9c-95d2-1f6386843c24'	System	24 Jan 2021 13:08:34
User entered 'No (N)'	System	24 Jan 2021 13:08:34

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-01-24T06:08:28', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3caae334-eaa3-4b9c-95d2-1f6386843c24'	System	24 Jan 2021 13:08:34
User entered 'No (N)'	System	24 Jan 2021 13:08:34

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-01-24T06:08:30', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3caae334-eaa3-4b9c-95d2-1f6386843c24'	System	24 Jan 2021 13:08:34
User entered '24 Jan 2021 06:08:30'	System	24 Jan 2021 13:08:34

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-01-31T09:41:57', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ac92a96e-1ea4-49a1-be72-c46f027c7210'	System	31 Jan 2021 17:42:06
User entered 'No (N)'	System	31 Jan 2021 17:42:06

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-01-31T09:41:59', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ac92a96e-1ea4-49a1-be72-c46f027c7210'	System	31 Jan 2021 17:42:06
User entered 'No (N)'	System	31 Jan 2021 17:42:06

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-01-31T09:42:02', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ac92a96e-1ea4-49a1-be72-c46f027c7210'	System	31 Jan 2021 17:42:06
User entered '31 Jan 2021 09:42:02'	System	31 Jan 2021 17:42:06

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-02-07T07:38:05', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fd13d5e3-f7a0-4ef6-ae36-023a9c7c8522'	System	07 Feb 2021 15:38:14
User entered 'No (N)'	System	07 Feb 2021 15:38:14

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-02-07T07:38:10', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fd13d5e3-f7a0-4ef6-ae36-023a9c7c8522'	System	07 Feb 2021 15:38:14
User entered 'No (N)'	System	07 Feb 2021 15:38:14

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-02-07T07:38:12', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'fd13d5e3-f7a0-4ef6-ae36-023a9c7c8522'	System	07 Feb 2021 15:38:14
User entered '07 Feb 2021 07:38:12'	System	07 Feb 2021 15:38:14

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-02-18T07:01:37', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'f6b12276-a32c-4831-b96b-093b0dc2ce5b'	System	18 Feb 2021 15:01:48
User entered 'No (N)'	System	18 Feb 2021 15:01:48

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-02-18T07:01:41', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'f6b12276-a32c-4831-b96b-093b0dc2ce5b'	System	18 Feb 2021 15:01:48
User entered 'No (N)'	System	18 Feb 2021 15:01:48

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-02-18T07:01:44', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'f6b12276-a32c-4831-b96b-093b0dc2ce5b'	System	18 Feb 2021 15:01:48
User entered '18 Feb 2021 07:01:44'	System	18 Feb 2021 15:01:48

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-02-21T19:16:33', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '513637e9-9524-4ecb-a650-4cf04db14c39'	System	22 Feb 2021 03:16:45
User entered 'No (N)'	System	22 Feb 2021 03:16:45

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-02-21T19:16:36', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '513637e9-9524-4ecb-a650-4cf04db14c39'	System	22 Feb 2021 03:16:45
User entered 'No (N)'	System	22 Feb 2021 03:16:45

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-02-21T19:16:42', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '513637e9-9524-4ecb-a650-4cf04db14c39'	System	22 Feb 2021 03:16:45
User entered '21 Feb 2021 19:16:42'	System	22 Feb 2021 03:16:45

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-03-07T07:01:24-08:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '7bd0549a-bfef-4b44-81db-74f7ae9c3743'	System	07 Mar 2021 15:01:41
User entered 'No (N)'	System	07 Mar 2021 15:01:41

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-03-07T07:01:34-08:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '7bd0549a-bfef-4b44-81db-74f7ae9c3743'	System	07 Mar 2021 15:01:41
User entered 'No (N)'	System	07 Mar 2021 15:01:41

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-03-07T07:01:38-08:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '7bd0549a-bfef-4b44-81db-74f7ae9c3743'	System	07 Mar 2021 15:01:41
User entered '07 Mar 2021 07:01:38'	System	07 Mar 2021 15:01:41

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-03-14T16:11:00-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '13cac4da-d874-4a79-b89d-6b14e52815e2'	System	14 Mar 2021 23:11:12
User entered 'No (N)'	System	14 Mar 2021 23:11:12

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-03-14T16:11:02-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '13cac4da-d874-4a79-b89d-6b14e52815e2'	System	14 Mar 2021 23:11:12
User entered 'No (N)'	System	14 Mar 2021 23:11:12

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-03-14T16:11:05-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '13cac4da-d874-4a79-b89d-6b14e52815e2' User entered '14 Mar 2021 16:11:05'	System	14 Mar 2021 23:11:12
	System	14 Mar 2021 23:11:12

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-03-21T05:57:04-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3e2c3a9c-51f9-4c7f-888c-6d104bb57ba2'	System	21 Mar 2021 12:57:16
User entered 'No (N)'	System	21 Mar 2021 12:57:16

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-03-21T05:57:09-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3e2c3a9c-51f9-4c7f-888c-6d104bb57ba2'	System	21 Mar 2021 12:57:16
User entered 'No (N)'	System	21 Mar 2021 12:57:16

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-03-21T05:57:11-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3e2c3a9c-51f9-4c7f-888c-6d104bb57ba2'	System	21 Mar 2021 12:57:16
User entered '21 Mar 2021 05:57:11'	System	21 Mar 2021 12:57:16

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-03-29T14:35:16-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '646f1704-1f86-47ff-94e6-688e850ac3e2'	System	29 Mar 2021 21:35:24
User entered 'No (N)'	System	29 Mar 2021 21:35:24

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-03-29T14:35:18-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '646f1704-1f86-47ff-94e6-688e850ac3e2'	System	29 Mar 2021 21:35:24
User entered 'No (N)'	System	29 Mar 2021 21:35:24

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-03-29T14:35:20-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '646f1704-1f86-47ff-94e6-688e850ac3e2' User entered '29 Mar 2021 14:35:20'	System	29 Mar 2021 21:35:24
	System	29 Mar 2021 21:35:24

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-04-04T06:29:41-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6cff9563-8b1c-4e2b-88c8-fecf8576946b'	System	04 Apr 2021 13:29:52
User entered 'No (N)'	System	04 Apr 2021 13:29:52

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-04-04T06:29:43-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6cff9563-8b1c-4e2b-88c8-fecf8576946b'	System	04 Apr 2021 13:29:52
User entered 'No (N)'	System	04 Apr 2021 13:29:52

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-04-04T06:29:47-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '6cff9563-8b1c-4e2b-88c8-fecf8576946b'	System	04 Apr 2021 13:29:52
User entered '04 Apr 2021 06:29:47'	System	04 Apr 2021 13:29:52

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-04-11T04:26:33-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ee5be44d-0ad8-4201-90c3-7e62dd5013ce'	System	11 Apr 2021 11:26:49
User entered 'No (N)'	System	11 Apr 2021 11:26:49

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-04-11T04:26:36-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ee5be44d-0ad8-4201-90c3-7e62dd5013ce'	System	11 Apr 2021 11:26:49
User entered 'No (N)'	System	11 Apr 2021 11:26:49

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-04-11T04:26:38-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: 'ee5be44d-0ad8-4201-90c3-7e62dd5013ce' User entered '11 Apr 2021 04:26:38'	System	11 Apr 2021 11:26:49
	System	11 Apr 2021 11:26:49

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-04-18T06:59:54-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1fd12aaa-4973-4c57-b5d5-3136338ce71b'	System	18 Apr 2021 14:00:03
User entered 'No (N)'	System	18 Apr 2021 14:00:03

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-04-18T06:59:57-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1fd12aaa-4973-4c57-b5d5-3136338ce71b'	System	18 Apr 2021 14:00:03
User entered 'No (N)'	System	18 Apr 2021 14:00:03

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-04-18T06:59:59-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '1fd12aaa-4973-4c57-b5d5-3136338ce71b'	System	18 Apr 2021 14:00:03
User entered '18 Apr 2021 06:59:59'	System	18 Apr 2021 14:00:03

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-04-25T06:43:50-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8c922b85-81e1-43aa-9f50-ae0d4bf18f3e'	System	25 Apr 2021 13:43:57
User entered 'No (N)'	System	25 Apr 2021 13:43:57

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-04-25T06:43:52-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8c922b85-81e1-43aa-9f50-ae0d4bf18f3e' User entered 'No (N)'	System	25 Apr 2021 13:43:57
	System	25 Apr 2021 13:43:57

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-04-25T06:43:54-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '8c922b85-81e1-43aa-9f50-ae0d4bf18f3e'	System	25 Apr 2021 13:43:57
User entered '25 Apr 2021 06:43:54'	System	25 Apr 2021 13:43:57

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[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 (471e01af26465b51)', Time: '2021-05-03T10:33:53-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '653e28e7-25ba-43da-b2bc-c2d16d675bd0'	System	03 May 2021 17:34:15
User entered 'Yes (Y)'	System	03 May 2021 17:34:15

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

Have you been exposed to someone with 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 (471e01af26465b51)', Time: '2021-05-03T10:33:57-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '653e28e7-25ba-43da-b2bc-c2d16d675bd0'	System	03 May 2021 17:34:15
User entered 'No (N)'	System	03 May 2021 17:34:15

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 (471e01af26465b51)', Time: '2021-05-03T10:34:04-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '653e28e7-25ba-43da-b2bc-c2d16d675bd0'	System	03 May 2021 17:34:15
User entered 'No (N)'	System	03 May 2021 17:34:15

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

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 (471e01af26465b51)', Time: '2021-05-03T10:34:07-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '653e28e7-25ba-43da-b2bc-c2d16d675bd0'	System	03 May 2021 17:34:15
User entered 'No (N)'	System	03 May 2021 17:34:15

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-05-03T10:34:11-07:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '653e28e7-25ba-43da-b2bc-c2d16d675bd0'	System	03 May 2021 17:34:15
User entered '03 May 2021 10:34:11'	System	03 May 2021 17:34:15

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 09:42:38

US3582154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:38
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 09:42:38

US3582154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:01:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-03-05T11:40:12-08:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3aef9d66-d9eb-4fc5-8451-d6e4923ba9e6'	System	05 Mar 2021 19:40:51
User entered 'Yes (Y)'	System	05 Mar 2021 19:40:51

US3582154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:01:28

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-03-05T11:40:34-08:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3aef9d66-d9eb-4fc5-8451-d6e4923ba9e6'	System	05 Mar 2021 19:40:51
User entered 'No (N)'	System	05 Mar 2021 19:40:51

US3582154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:01:28

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (471e01af26465b51)', Time: '2021-03-05T11:40:36-08:00', User OID: 'PatientReportedOutcome (US3582154)', ODM File OID: '3aef9d66-d9eb-4fc5-8451-d6e4923ba9e6'	System	05 Mar 2021 19:40:51
User entered '05 Mar 2021 11:40:36'	System	05 Mar 2021 19:40:51

US3582154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:52:59
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	11 Dec 2020 01:02:45

US3582154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:52:59
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered '8 Dec 2020'	Roxanne Erolin (b) (4) (b) (4)	11 Dec 2020 01:02:45

US3582154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:52:59
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Contact Made (CONTACT MADE)'	Roxanne Erolin (b) (4) (b) (4)	11 Dec 2020 01:02:45

US3582154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:52:59
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	11 Dec 2020 01:02:45

US3582154

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
DataPoint Verified.	(b) (4)	18 Feb 2021 20:53:54
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:54:37

US3582154

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:28:42
User entered 'l'	System	13 Jan 2021 17:54:37

US3582154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:54:11
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:54:52

US3582154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4)	18 Feb 2021 20:54:11
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '11 Jan 2021'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:54:52

US3582154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:54:11
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Contact Made (CONTACT MADE)'	Stella Lee (b) (4)	13 Jan 2021 17:54:52

US3582154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:54:11
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:54:52

US3582154

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:55:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	10 Feb 2021 22:15:15

US3582154

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User entered 'l'	System	10 Feb 2021 22:15:15

US3582154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4)	8 Feb 2021 20:55:15
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	10 Feb 2021 22:15:28

US3582154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4)	18 Feb 2021 20:55:15
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '08 Feb 2021'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	10 Feb 2021 22:15:28

US3582154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:55:15
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Contact Made (CONTACT MADE)'	Roxanne Erolin (b) (4) (b) (4)	10 Feb 2021 22:15:28

US3582154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:55:15
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	10 Feb 2021 22:15:28

US3582154

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 00:21:03
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4)	19 Feb 2021 17:30:24

US3582154

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User entered 'l'	System	19 Feb 2021 17:30:24

US3582154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:52:43
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	11 Mar 2021 23:51:09

US3582154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:52:43
User entered '11 Mar 2021'	Roxanne Erolin (b) (4) (b) (4)	11 Mar 2021 23:51:09

US3582154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:52:43
User entered 'Contact Made (CONTACT MADE)'	Roxanne Erolin (b) (4) (b) (4)	11 Mar 2021 23:51:09

US3582154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:52:43
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	11 Mar 2021 23:51:09

US3582154

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:52:47
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	11 Mar 2021 23:52:08

US3582154

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:32:45
User entered 'l'	System	11 Mar 2021 23:52:08

US3582154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:14:26
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:38

US3582154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:14:26
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Marilyn Nguyen (b) (4)	06 Apr 2021 17:11:38

US3582154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:14:26
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Clinic (Clinic)'	(b) (4) Marilyn Nguyen (b) (4)	06 Apr 2021 17:11:38

US3582154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	06 Apr 2021 17:11:38

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered 'No (N)'	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:11:51

US3582154

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:04
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:12:35

US3582154

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:04
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Marilyn Nguyen (b) (4)	06 Apr 2021 17:12:35

US3582154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:12:52

US3582154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:22
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Marilyn Nguyen (b) (4)	06 Apr 2021 17:12:52

US3582154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered '14:45'	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:12:52

US3582154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Apr 2021 14:45'	System	06 Apr 2021 17:12:52

US3582154

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:25
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	06 Apr 2021 17:13:01

US3582154

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 17:13:01

US3582154

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

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:07
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:50:50

US3582154

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

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:07
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered '03 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:50:50

US3582154

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

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:07
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Clinic (Clinic)'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:50:50

US3582154

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

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 21:50:50

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 00:20:26
DataPoint Un-verified.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:48:00
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:48:00
User entered '03 Feb 2021' reason for change: New Information	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:48:00
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:19
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered '06 Jan 2021'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:51:46

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[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 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:43:23
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 22:28:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:12:29

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:19
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:51:46

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:43:25
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Mar 2021 22:28:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:12:29

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:19
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered '03 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:51:46

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:19
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Placebo (Placebo)'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:51:46

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:19
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Placebo (Placebo)'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:51:46

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:19
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'Placebo (Placebo)'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:51:46

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:43:31
DataPoint Un-verified.	Stella Lee (b) (4)	09 Mar 2021 21:44:32
Signature has been broken.	Stella Lee (b) (4)	09 Mar 2021 21:44:32
User entered 'Yes (Y)' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:44:32
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:56:19
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered 'No (N)' reason for change: New Information	Stella Lee (b) (4)	05 Feb 2021 22:00:53
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	04 Feb 2021 21:51:46

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '1'	System	04 Feb 2021 21:51:46

US3582154

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

Form: Unblinding

Generated On: 11 Aug 2021 23:01:28

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '1'	System	09 Mar 2021 21:44:32
User entered empty.	System	05 Feb 2021 22:00:53
User entered '1'	System	04 Feb 2021 21:51:46

US3582154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:57:42
User closed query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:57:08
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 17:57:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:57:03
Query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' answered with 'addressed' (Site from CRA).	Stella Lee (b) (4)	22 Mar 2021 14:46:04
User entered missing code ND - Not Done; reason for change Per Query Resolution	Stella Lee (b) (4)	22 Mar 2021 14:45:53
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User opened query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 19:44:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data no required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty.	Stella Lee (b) (4)	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:57:44
User closed query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:57:11
Query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' answered with 'addressed' (Site from CRA).	Stella Lee (b) (4)	22 Mar 2021 14:46:27
User entered missing code ND - Not Done; reason for change Per Query Resolution	Stella Lee (b) (4)	22 Mar 2021 14:45:53
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:16
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User opened query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 19:44:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint set to visible.	System	09 Mar 2021 21:44:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
DataPoint set to invisible.	System	05 Feb 2021 22:00:53
User entered empty.	System	05 Feb 2021 22:00:17
DataPoint set to visible.	System	04 Feb 2021 21:51:46

US3582154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:57:42
User closed query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).		22 Mar 2021 17:57:08
DataPoint Un-verified.		22 Mar 2021 17:57:06
DataPoint Verified.		22 Mar 2021 17:57:03
Query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' answered with 'addressed' (Site from CRA).	Stella Lee (b) (4)	22 Mar 2021 14:46:04
User entered missing code ND - Not Done; reason for change Per Query Resolution	Stella Lee (b) (4)	22 Mar 2021 14:45:53
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:14
DataPoint Verified.		18 Mar 2021 19:47:11
User opened query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).		18 Mar 2021 19:44:04
DataPoint activated with code reason code Data required.		08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data no required.		18 Feb 2021 21:02:09
Signature has been broken.		18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:57:44
User closed query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:57:11
Query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' answered with 'addressed' (Site from CRA).	Stella Lee (b) (4)	22 Mar 2021 14:46:27
User entered missing code ND - Not Done; reason for change Per Query Resolution	Stella Lee (b) (4)	22 Mar 2021 14:45:53
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:16
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User opened query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 19:44:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data no required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty.	Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint set to visible.	System	09 Mar 2021 21:44:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
DataPoint set to invisible.	System	05 Feb 2021 22:00:53
User entered empty.	System	05 Feb 2021 22:00:17
DataPoint set to visible.	System	04 Feb 2021 21:51:46

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered 'Yes (Y)' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 06:20:56
Query 'Data is required. Please complete.' answered with 'ppt didn't receive vax at OL-D1 visit' (Site from System).	Stella Lee (b) (4)	05 Feb 2021 22:01:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 22:01:24
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered 'Yes (Y)'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '05 Mar 2021' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered '03 Feb 2021'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '11:04' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered '10:16'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '05 Mar 2021 11:04'	System	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User entered empty.	System	05 Feb 2021 22:01:24
User entered '03 Feb 2021 10:16'	System	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '98.8' F reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered '99.6' F	Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered 'Other (Other)' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered 'Other (Other)'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered 'Temporal' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered 'Temporal'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '68' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered '73'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'bpm'	System	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User entered empty.	System	05 Feb 2021 22:01:24
User entered 'bpm'	System	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '16' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered '12'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'breaths/min'	System	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User entered empty.	System	05 Feb 2021 22:01:24
User entered 'breaths/min'	System	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '110' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered '116'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'mmHg'	System	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User entered empty.	System	05 Feb 2021 22:01:24
User entered 'mmHg'	System	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '69' reason for change: New Information	Stella Lee (b) (4)	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty; reason for change Data Entry Error	Stella Lee (b) (4)	05 Feb 2021 22:01:24
User entered '67'	Stella Lee (b) (4)	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'mmHg'	System	09 Mar 2021 21:50:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User entered empty.	System	05 Feb 2021 22:01:24
User entered 'mmHg'	System	05 Feb 2021 22:00:17

US3582154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:57:42
User closed query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:57:08
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 17:57:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:57:03
Query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' answered with 'addressed' (Site from CRA).	Stella Lee (b) (4)	22 Mar 2021 14:46:04
User entered missing code ND - Not Done; reason for change Per Query Resolution	Stella Lee (b) (4)	22 Mar 2021 14:45:53
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User opened query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 19:44:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data no required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
Signature has been broken.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User entered empty.	Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:57:44
User closed query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).		22 Mar 2021 17:57:11
Query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' answered with 'addressed' (Site from CRA).	Stella Lee (b) (4)	22 Mar 2021 14:46:27
User entered missing code ND - Not Done; reason for change Per Query Resolution	Stella Lee (b) (4)	22 Mar 2021 14:45:53
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:16
DataPoint Verified.		18 Mar 2021 19:47:11
User opened query 'Please enter data or not done, whichever is applicable. Per source, no data entered.' (Site from CRA).		18 Mar 2021 19:44:14
DataPoint activated with code reason code Data required.		08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data no required.		18 Feb 2021 21:02:09
Signature has been broken.		18 Feb 2021 21:02:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:00:17

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint set to visible.	System	09 Mar 2021 21:44:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09
DataPoint set to invisible.	System	05 Feb 2021 22:00:53
User entered empty.	System	05 Feb 2021 22:00:17
DataPoint set to visible.	System	04 Feb 2021 21:51:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User accepted default value 'Post-Dose (POSTDOSE)'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered 'Yes (Y)'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '05 Mar 2021'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '12:03'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '05 Mar 2021 12:03'	System	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '97.4' F	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered 'Oral (Oral)'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered empty.	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

US3582154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '71'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'bpm'	System	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

US3582154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '16'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

US3582154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'breaths/min'	System	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

US3582154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '108'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'mmHg'	System	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

US3582154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:47:11
User entered '64'	Stella Lee (b) (4)	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'mmHg'	System	09 Mar 2021 21:50:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Mar 2021 23:44:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Feb 2021 21:02:09

US3582154

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

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:19
User entered 'Yes (Y)'	Stella Lee (b) (4)	09 Mar 2021 21:51:02

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

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:19
User entered '05 Mar 2021'	Stella Lee (b) (4)	09 Mar 2021 21:51:02

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:37
User entered 'Yes (Y)'	Stella Lee (b) (4)	09 Mar 2021 21:51:27

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:37
User entered '05 Mar 2021'	Stella Lee (b) (4)	09 Mar 2021 21:51:27

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:37
User entered 'Urine (URINE)'	Stella Lee (b) (4)	09 Mar 2021 21:51:27

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:37
User entered 'Negative (NEGATIVE)'	Stella Lee (b) (4)	09 Mar 2021 21:51:27

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:37
User entered 'No (N)' reason for change: New Information	Melissa Scheer (b) (4) (b) (4)	09 Mar 2021 23:51:47
User entered empty.	Stella Lee (b) (4)	09 Mar 2021 21:51:27

US3582154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:37
User entered empty.	Stella Lee (b) (4)	09 Mar 2021 21:51:27

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:37
User entered empty.	Stella Lee (b) (4)	09 Mar 2021 21:51:27

US3582154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered empty.	System	09 Mar 2021 21:51:27

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:43
User entered 'Yes (Y)'	Stella Lee (b) (4)	09 Mar 2021 21:51:49

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:43
User entered empty.	Stella Lee (b) (4)	09 Mar 2021 21:51:49

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:43
User entered empty.	Stella Lee (b) (4)	09 Mar 2021 21:51:49

US3582154

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'mRNA-1273'	System	09 Mar 2021 21:51:49
DataPoint set to visible.	System	09 Mar 2021 21:44:32

US3582154

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:43
User entered '05 Mar 2021'	Stella Lee (b) (4)	09 Mar 2021 21:51:49

US3582154

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:43
User entered '11:33'	Stella Lee (b) (4)	09 Mar 2021 21:51:49

US3582154

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '05 Mar 2021 11:33'	System	09 Mar 2021 21:51:49

US3582154

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:48:43
User entered 'Left Arm (LEFT ARM)'	Stella Lee (b) (4)	09 Mar 2021 21:51:49

US3582154

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.		18 Mar 2021 19:48:43
User entered 'ONCE'		09 Mar 2021 21:51:49

US3582154

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

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 21:51:49

US3582154

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:02:23
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:02:16

US3582154

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:02:23
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '03 Feb 2021'	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:02:16

US3582154

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:02:23
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '10:29'	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:02:16

US3582154

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '03 Feb 2021 10:29'	System	05 Feb 2021 22:02:16

US3582154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:01:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:02:30
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:02:25

US3582154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:01:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:02:30
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '03 Feb 2021'	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:02:25

US3582154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:01:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:02:30
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '10:36'	(b) (4) Stella Lee (b) (4)	05 Feb 2021 22:02:25

US3582154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:01:28

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered '03 Feb 2021 10:36'	System	05 Feb 2021 22:02:25

US3582154

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

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:00
User entered 'Yes (Y)'	Stella Lee (b) (4)	09 Mar 2021 21:51:53

US3582154

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

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:17
User entered 'l'	System	09 Mar 2021 21:51:53

US3582154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:10
User entered 'Yes (Y)'	Stella Lee (b) (4)	15 Mar 2021 20:23:36

US3582154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:10
User entered '12 Mar 2021'	Stella Lee (b) (4)	15 Mar 2021 20:23:36

US3582154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:10
User entered 'Contact Made (CONTACT MADE)'	Stella Lee (b) (4)	15 Mar 2021 20:23:36

US3582154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:10
User entered empty.	Stella Lee (b) (4)	15 Mar 2021 20:23:36

US3582154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:49:32
User entered 'Yes (Y)'	Stella Lee (b) (4)	15 Mar 2021 20:24:02

US3582154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:10
User entered 'l'	System	15 Mar 2021 20:24:02

US3582154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:10
User entered '1'	System	15 Mar 2021 20:24:02
DataPoint set to visible.	System	15 Mar 2021 20:24:02

US3582154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:40
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:03:59

US3582154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:40
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:03:59

US3582154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:40
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Clinic (Clinic)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:03:59

US3582154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	06 Apr 2021 20:03:59

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '14:30'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 14:30'	System	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '97.6' F	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Other (Other)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Temporal'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '71'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '12'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '119'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '77'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 20:04:34

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '15:44'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 15:44'	System	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '97.8' F	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Other (Other)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Temporal'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '65'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '12'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '119'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:17:46
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '70'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 20:05:06

US3582154

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:34
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:20

US3582154

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:34
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:20

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:08
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:40

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:08
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:40

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Test performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:08
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Urine (URINE)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:40

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Result](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:08
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Negative (NEGATIVE)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:40

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:08
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'No (N)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:40

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:08
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered empty.	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:40

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

[Collection time](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:08
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered empty.	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:40

US3582154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:28

Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:06:40

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:14
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:14
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered empty.	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:14
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered empty.	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	06 Apr 2021 20:06:59
DataPoint set to visible.	System	15 Mar 2021 20:24:02

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:14
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '05 Apr 2021'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:14
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered '15:14'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Apr 2021 15:14'	System	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:14
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:14
User entered 'ONCE'	System	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	06 Apr 2021 20:06:59

US3582154

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:19
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:31:31
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	06 Apr 2021 20:07:04

US3582154

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:07:04

US3582154

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 23:01:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:14:19
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:10:22

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Frontal headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:33:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:33:48
Data point term sent to Coder	System	28 Sep 2020 19:18:33
User entered 'headache, right frontal mild'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '24 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User entered empty.	System	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '25 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User entered empty.	System	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

Death

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4)	12 Mar 2021 17:17:05
Signature has been broken.	(b) (4)	
	Melissa Scheer (b) (4)	09 Mar 2021 23:54:30
User signature succeeded.	(b) (4)	
	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'l'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:51
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.		28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.		28 Apr 2021 14:16:51
User entered '0'	System	28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.		28 Apr 2021 14:16:51
User entered '0'		28 Sep 2020 19:17:49

US3582154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 14:17:20
Data hard locked.		28 Apr 2021 14:16:51

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:56:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:56:54
Data point term sent to Coder	System	01 Oct 2020 19:56:02
User entered 'urticaria'	Vi Tran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Vi Tran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '23 Sep 2020'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User entered empty.	System	01 Oct 2020 19:55:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 23:25:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 23:25:23
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 23:25:23
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:55:04
User entered empty.	Vi Tran (b) (4) (b) (4)	01 Oct 2020 19:55:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '26 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 23:25:23
User entered empty.	Vi Tran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User entered empty.	System	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'None (NONE)'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'l'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 23:25:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 23:25:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 23:25:23
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:55:04
User entered empty.	Vi Tran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	V1 Iran (b) (4) (b) (4)	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User entered '0'	System	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57
User entered '0'	System	01 Oct 2020 19:55:04

US3582154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:16:57

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:48:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:48:08
Data point term sent to Coder	System	16 Oct 2020 21:28:08
User closed query 'DM-Coding: please provide location and update this term in accordance with your answer. (ex-l, Ear congestion/Nasal congestion/Renal venous congestion and etc.)' (Site from System).	System	16 Oct 2020 21:27:34
Query 'DM-Coding: please provide location and update this term in accordance with your answer. (ex-l, Ear congestion/Nasal congestion/Renal venous congestion and etc.)' answered with 'updated' (Site from System).	Melissa Scheer (b) (4) (b) (4)	16 Oct 2020 21:27:34
User entered 'NASAL CONGESTION' reason for change: Data Entry Error	Melissa Scheer (b) (4) (b) (4)	16 Oct 2020 21:27:26
User opened query 'DM-Coding: please provide location and update this term in accordance with your answer. (ex-l, Ear congestion/Nasal congestion/Renal venous congestion and etc.)' (Site from System).	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:24:18
Data point term sent to Coder	System	15 Oct 2020 01:13:45
User entered 'congestion'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '14 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '04:00'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User entered '14 Oct 2020 04:00'	System	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 20:29:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 20:29:22
User entered 'No (N)' reason for change: New Information	Stella Lee (b) (4)	23 Oct 2020 20:29:22
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 01:13:34
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '15 Oct 2020' reason for change: New Information	Stella Lee (b) (4)	23 Oct 2020 20:29:22
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '08:00' reason for change: New Information	Stella Lee (b) (4)	23 Oct 2020 20:29:22
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User entered '15 Oct 2020 08:00'	System	23 Oct 2020 20:29:22
User entered empty.	System	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:17:57
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'Done!' (Site from DM).	Stella Lee (b) (4)	17 Nov 2020 22:56:47
DataPoint Un-verified.	Stella Lee (b) (4)	17 Nov 2020 22:56:33
User entered '0' reason for change: Data Entry Error	Stella Lee (b) (4)	17 Nov 2020 22:56:33
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 14:36:35
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed was given after the End date of this AE. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4)	15 Feb 2021 03:20:39
	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
	(b) (4)	
Query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed was given after the End date of this AE. Please review and update applicable details accordingly. Otherwise, clarify.' answered with 'clarification. Medication stop date corrected.' (Site from DM).	Paula Lins (b) (4)	11 Feb 2021 22:57:26
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed was given after the End date of this AE. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 17:33:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
DataPoint Un-verified.	Stella Lee (b) (4)	17 Nov 2020 22:56:33
User entered '1' reason for change: Data Entry Error	Stella Lee (b) (4)	17 Nov 2020 22:56:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'		15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 20:29:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 20:29:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Stella Lee (b) (4)	23 Oct 2020 20:29:22
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 01:13:34
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User entered '0'	System	15 Oct 2020 01:13:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02
User entered '0'	System	15 Oct 2020 01:13:34

US3582154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:02

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:00:33
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'Headache was not a worsening of ongoing MH headaches. Different in nature to usual headache, Resolved in 2 hours with ibuprofen.' (Site from DM).	Paula Lins (b) (4) (b) (4)	30 Dec 2020 20:25:04
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 23:42:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:31:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:31:44
Data point term sent to Coder	System	23 Oct 2020 20:30:57
User entered 'Headache'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '16 Oct 2020'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User entered empty.	System	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '16 Oct 2020'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User entered empty.	System	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'None (NONE)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'l'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User entered '0'	System	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
User entered '0'	System	23 Oct 2020 20:30:22

US3582154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:10

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:26:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:26:50
Data point term sent to Coder	System	30 Oct 2020 00:37:40
User entered 'Nasal congestion, intermittent'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 22:36:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 00:37:35
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '22 Oct 2020'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User entered empty.	System	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '23 Oct 2020'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User entered empty.	System	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Applicable (NOT APPLICABLE)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'l'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User entered '0'	System	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35
User entered '0'	System	30 Oct 2020 00:37:35

US3582154

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:35

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User coded data point as SOC: Gastrointestinal disorders, HLT: Dental and gingival conditions, HLT: Gingival disorders, signs and symptoms NEC, PT: Noninfective gingivitis, LLT: Gingival inflammation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:04:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:04:45
Data point term sent to Coder	System	09 Nov 2020 21:39:19
User entered 'gingival inflammation due to bracket of braces. Right upper tooth (#3)'	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Yes (Y)'	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '2 Nov 2020'	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User entered empty.	System	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)' reason for change: New Information	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:21:10
User entered 'Yes (Y)'	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '8 Nov 2020' reason for change: New Information	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:21:10
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User entered empty.	System	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'No (N)'	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Related (NOT RELATED)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'Not Applicable (NOT APPLICABLE)'	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered 'l'	Vi Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered '0'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 01:21:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 01:21:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Roxanne Erolin (b) (4) (b) (4)	12 Nov 2020 01:21:10
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:38:55
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:56:28
User entered empty.	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User entered '0'	System	09 Nov 2020 21:38:55

US3582154

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58
User entered 'l'	System	09 Nov 2020 21:38:55

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:43:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:04:04
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'symptoms did not persist beyond 48 hours, therefore did not meet criteria for illness visit.' (Site from DM).	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:56:00
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:21:51
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:57:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:57:51
Data point term sent to Coder	System	17 Nov 2020 22:56:09
User entered 'Sinus congestion'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '24 Sep 2020'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User entered empty.	System	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '26 Sep 2020'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User entered empty.	System	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'Not Related (NOT RELATED)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'Not Related (NOT RELATED)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

Form: Adverse Events (8)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'None (NONE)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'l'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User entered '0'	System	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57
User entered '0'	System	17 Nov 2020 22:55:43

US3582154

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:57

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:03:56
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'symptom did not persist beyond 48 hours, therefore did not meet criteria for illness visit.' (Site from DM).	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 22:57:04
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:23:57
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Postnasal drip - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:58:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 22:58:55
Data point term sent to Coder	System	17 Nov 2020 22:58:10
User entered 'Post nasal drainage'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '24 Sep 2020'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User entered empty.	System	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '26 Sep 2020'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User entered empty.	System	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'No (N)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'Not Related (NOT RELATED)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'Not Related (NOT RELATED)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'None (NONE)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'l'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered '0'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:28:43
User entered empty.	Stella Lee (b) (4)	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User entered '0'	System	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02
User entered '0'	System	17 Nov 2020 22:57:38

US3582154

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:01:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:44:02

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:01:28

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:14:19
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4)	31 Mar 2021 05:38:03
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'This has been added to Med History' (Site from DM).	Melissa Scheer (b) (4) (b) (4)	30 Mar 2021 17:25:05
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:56:56
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:10
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:25:37

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:27:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:27:45
Data point term sent to Coder	System	21 Sep 2020 22:27:08
User entered 'Nuvaring'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Birth control'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 22:03:39
Signature has been broken.	(b) (4) Paula Lins (b) (4)	12 Mar 2021 17:53:53
User signature succeeded.	(b) (4) Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '1'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Other (OTHER)'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'ring'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'every month (QM)'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Vaginal (VAGINAL)'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'UN UNK 2014'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:57:06
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 23:45:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 23:45:31
User entered 'No (N)' reason for change: Data Entry Error	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:45:31
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 23:45:25
DataPoint Un-verified.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:45:25
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:45:25
User entered empty; reason for change Data Entry Error	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:45:25
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
User closed query 'Please enter end date. Per source, 30Nov20 documented.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 17:57:03
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:57:00
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	24 Feb 2021 23:45:25
Query 'Please enter end date. Per source, 30Nov20 documented.' answered with 'updated' (Site from CRA).	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:45:19
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	24 Feb 2021 23:45:07
DataPoint Un-verified.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:45:07
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:45:07
User entered '30 Nov 2020' reason for change: Data Entry Error	Melissa Scheer (b) (4) (b) (4)	24 Feb 2021 23:45:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 21:03:51
User opened query 'Please enter end date. Per source, 30Nov20 documented.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 21:03:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User entered '1'	System	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User entered '1'	System	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:49
User entered '802 (802)'	System	21 Sep 2020 22:26:12

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE NASAL MIST - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 05:56:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 05:56:51
Data point term sent to Coder	System	21 Sep 2020 22:27:10
User entered 'Saline nasal mist'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Seasonal allergies'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '1'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Other (OTHER)'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Spray'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'as needed (PRN)'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Nasal (NASAL)'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '1'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:26:43

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	21 Sep 2020 22:28:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 22:28:46
Data point term sent to Coder User entered 'Cetirizine'	System Stella Lee (b) (4)	21 Sep 2020 22:28:13 21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Seasonal allergies'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '10'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'mg (mg)'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'as needed (PRN)'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Oral (ORAL)'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '14 Jul 2018'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:27:35

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 22:28:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 22:28:45
Data point term sent to Coder User entered 'Flonase'	System Stella Lee (b) (4)	21 Sep 2020 22:28:13 21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Seasonal allergies'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of sprays, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	09 Nov 2020 04:26:06
' (Site from DM). Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of sprays, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	05 Nov 2020 16:29:44
' answered with 'Per the patients Epic Chart. ' (Site from DM). User entered '50' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Nov 2020 16:29:01
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of sprays, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	03 Nov 2020 08:44:33
' (Site from DM). User entered '2'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 16:30:56
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	05 Nov 2020 16:29:01
User entered 'ug (ug)' reason for change: Per Query Resolution	System	05 Nov 2020 16:29:01
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Nov 2020 16:29:01
	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:30:56
User entered 'sprays'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'as needed (PRN)'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Nasal (NASAL)'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'UN UNK 2015'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:28:05

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:29:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:29:46
Data point term sent to Coder	System	21 Sep 2020 22:29:14
User entered 'Multivitamin'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Health maintenance'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '2'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Other (OTHER)'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Gummies'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'once daily (QD)'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Oral (ORAL)'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'UN Jul 2020'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '0'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Un-verified.	(b) (4) Marilyn Nguyen (b) (4)	04 Feb 2021 21:46:49
User entered 'No (N)' reason for change: New Information	(b) (4) Marilyn Nguyen (b) (4)	04 Feb 2021 21:46:49
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
DataPoint Verified.	(b) (4)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Un-verified.	(b) (4)	(b) (4)
	Marilyn Nguyen (b) (4)	04 Feb 2021 21:46:49
User entered '01 Jan 2021' reason for change: New Information	(b) (4)	(b) (4)
	Marilyn Nguyen (b) (4)	04 Feb 2021 21:46:49
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User entered '1'	System	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User entered '1'	System	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:44:53
User entered '804 (804)'	System	21 Sep 2020 22:28:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
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.	Coder Import (b) (4)	22 Sep 2020 12:03:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 12:03:40
Data point term sent to Coder	System	21 Sep 2020 22:29:14
User entered 'Ibuprofen'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Headache or muscle pain from activity'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '400'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'mg (mg)'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'as needed (PRN)'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Oral (ORAL)'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '1'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Stella Lee (b) (4)	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:29:08

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE, PRODUCTSYNONYM: AFRIN [OXYMETAZOLINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 11:21:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 11:21:44
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 22:03:39
Data point term sent to Coder Coding entries removed.	System Melissa Scheer (b) (4)	30 Mar 2021 17:24:00 30 Mar 2021 17:23:29
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:35:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE, PRODUCTSYNONYM: AFRIN [OXYMETAZOLINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 06:10:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 06:10:41
Data point term sent to Coder	System	16 Mar 2021 22:09:48
User closed query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding. (Site from System).	System	16 Mar 2021 22:09:02
Query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding. answered with 'updated' (Site from System).	Melissa Scheer (b) (4)	16 Mar 2021 22:09:02

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'AFRIN 0.05% [Oxymetazoline]' reason for change: Per Query Resolution	Melissa Scheer (b) (4)	16 Mar 2021 22:08:55
User opened query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding. '(Site from System).	(b) (4)	
Data point term sent to Coder DataPoint Un-verified.	Coder Import (b) (4)	15 Mar 2021 05:16:08
	(b) (4)	
Coding entries removed.	System	12 Mar 2021 17:50:25
Signature has been broken.	Paula Lins (b) (4)	12 Mar 2021 17:50:25
	(b) (4)	
User entered 'AFRIN 0.05%' reason for change: Data Entry Error	Paula Lins (b) (4)	12 Mar 2021 17:50:25
User signature succeeded.	Paula Lins (b) (4)	12 Mar 2021 17:50:25
	(b) (4)	
DataPoint Verified.	Paula Lins (b) (4)	12 Mar 2021 17:50:25
	(b) (4)	
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: SYMPATHOMIMETICS USED AS DECONGESTANTS, PRODUCT: OXYMETAZOLINE, PRODUCTSYNONYM: AFRIN [OXYMETAZOLINE] - version WHODrug-Global-B3\202003.	Paula Lins (b) (4)	12 Mar 2021 17:50:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
Data point term sent to Coder	(b) (4)	
User entered 'afrin'	(b) (4), (b) (6)	12 Nov 2020 22:02:16
	(b) (4)	
	Coder Import (b) (4)	15 Oct 2020 20:47:01
	(b) (4)	
	Coder Import (b) (4)	15 Oct 2020 20:47:01
	(b) (4)	
	System	15 Oct 2020 01:10:43
	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'		15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
DataPoint Verified.	(b) (4)	14 Apr 2021 19:12:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of Congestion. Review and update indication and ensure to update Adverse event eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:37:26
Query 'Per DM CLR: Please update the indication to reflect the location and type of Congestion. Review and update indication and ensure to update Adverse event eCRF as appropriate. answered with 'updated' (Site from DM).	Melissa Scheer (b) (4) (b) (4)	30 Mar 2021 17:24:00
DataPoint Un-verified.	Melissa Scheer (b) (4) (b) (4)	30 Mar 2021 17:23:29
Signature has been broken.	Melissa Scheer (b) (4) (b) (4)	30 Mar 2021 17:23:29
User entered 'Nasal CONGESTION' reason for change: Data Entry Error	Melissa Scheer (b) (4) (b) (4)	30 Mar 2021 17:23:29
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of Congestion. Review and update indication and ensure to update Adverse event eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:18:42
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'congestion'	(b) (4)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of spray 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)	15 Mar 2021 07:35:11
Query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'dose was 1 spray of 0.05% strength afrin' (Site from DM).	Paula Lins (b) (4) (b) (4)	12 Mar 2021 17:50:53
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of spray 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)	09 Mar 2021 00:43:07
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'l'	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User entered 'spray'	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'as needed (PRN)'	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '14 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '0'		15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
DataPoint Verified.	(b) (4)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Un-verified.	(b) (4)	
	Paula Lins (b) (4)	11 Feb 2021 22:56:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Paula Lins (b) (4)	11 Feb 2021 22:56:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Un-verified.	(b) (4) Paula Lins (b) (4)	11 Feb 2021 22:56:55
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4) Paula Lins (b) (4)	11 Feb 2021 22:56:55
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User entered empty.	System	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User entered empty.	System	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:00
User entered empty.	System	15 Oct 2020 01:10:40

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
DataPoint Verified.	(b) (4)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	23 Dec 2020 17:59:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:59:48
Data point term sent to Coder	System	22 Dec 2020 23:04:38
User closed query 'CDM-Coding: For Coding Purpose, please update the term according to query response 'Ingredients- zinc acetate, zinc gluconate' (Site from System).	System	22 Dec 2020 23:04:02
Query 'CDM-Coding: For Coding Purpose, please update the term according to query response 'Ingredients- zinc acetate, zinc gluconate' answered with 'updated' (Site from System).	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 23:04:02
DataPoint Un-verified.	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 23:03:55
User entered 'ZICAM RAPID MELTS: ingredients-zinc acetate, zinc gluconate' reason for change: Per Query Resolution	Diana McFeters (b) (4) (b) (4)	22 Dec 2020 23:03:55
User opened query 'CDM-Coding: For Coding Purpose, please update the term according to query response 'Ingredients- zinc acetate, zinc gluconate' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:21:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
Data point term sent to Coder	System	05 Nov 2020 16:37:20
User closed query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	05 Nov 2020 16:36:33

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

Name of Medication

Audit	User	Time (GMT)
Query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'Ingredients- zinc acetate, zinc gluconate' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 16:36:33
User entered 'ZICAM Rapid melts' reason for change: Per Query Resolution		05 Nov 2020 16:36:24
User opened query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	01 Nov 2020 14:10:46
Data point term sent to Coder	System	30 Oct 2020 00:39:41
User entered 'Zicam'	Roxanne Erolin (b) (4)	30 Oct 2020 00:38:48
	(b) (4)	

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Nasal congestion'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'l'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'tablet (TABLET)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'other (OTHER)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '5x/d'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Oral (ORAL)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '22 Oct 2020'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '0'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '23 Oct 2020'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User entered empty.	System	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User entered empty.	System	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:03
User entered empty.	System	30 Oct 2020 00:38:48

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
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.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:22:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:22:42
Data point term sent to Coder	System	09 Nov 2020 21:37:16
User entered 'ibuprofen'	Vi Tran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'gingival inflammation from braces bracket. Right upper tooth #3'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '400'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'mg (mg)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'as needed (PRN)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Oral (ORAL)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '2 Nov 2020'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '0'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '4 Nov 2020'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User entered empty.	System	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User entered empty.	System	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:14
User entered empty.	System	09 Nov 2020 21:36:27

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4)	12 Nov 2020 22:02:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE GLUCONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 03:52:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 03:52:41
Data point term sent to Coder	System	09 Nov 2020 21:38:17
User entered 'chlorhexidine gluconate 0.12%'	Vi Tran (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'gingival inflammation due to braces bracket right upper tooth #3'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '15'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'mL (mL)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'twice daily (BID)'	Vl Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Other (OTHER)'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'oral rinse'	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '5 Nov 2020'	VI Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered '0'	Vl Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'Yes (Y)'	VI Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered empty.	V1 Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:23:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:02:16
User entered 'No (N)'	Vl Iran (b) (4) (b) (4)	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 21:37:23

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
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)	13 Jan 2021 17:58:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 17:58:03
Data point term sent to Coder	System	13 Jan 2021 17:57:50
User entered 'Influenza vaccine'	Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Yes (Y)'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Health maintenance'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '0.5'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'mL (mL)'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'once (ONCE)'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered empty.	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '09 Dec 2020'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.		18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '0'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'No (N)'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered '09 Dec 2020'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:04:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:23:04
User entered 'No (N)'	(b) (4) Stella Lee (b) (4)	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
User entered empty.	System	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
User entered empty.	System	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:01:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:45:17
User entered empty.	System	13 Jan 2021 17:56:57

US3582154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:01:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 22:03:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 00:22:32
User entered 'No (N)'	Stephanie Pimienta (b) (4)	19 Feb 2021 17:30:19