US3642261 (Prod: University of California San Diego)

US3642261
Form: Participant Creation
Data signed: (b) (4) **13 Feb 2021 18:28:34**
Generated On: 11 Aug 2021 22:57:45

Participant ID US3642261

mRNA-1273-P301 Completion Guidelines

US3642261

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	19 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female ●
	Male ○
Ethnicity	Hispanic or Latino ●
	Not Hispanic or Latino ○
	Not Reported ○
	Unknown ○

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

Date of Informed Consent *(dd MMM yyyy)*	19 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

US3642261

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **13 Feb 2021 18:28:35**

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Did the participant meet all eligibility criteria?   Yes ●

No ◯

Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **13 Feb 2021 18:28:35**
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Were any significant conditions reported?   Yes ●

No ○

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	DEPENDENT EDEMA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN JUL 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
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)	

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	CONSTIPATION
Start date (dd MMM yyyy)	22 APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3642261

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	SPINAL STENOSIS OF LUMBAR REGION WITH RADICULOPATHY
Start date (dd MMM yyyy)	23 SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3642261

Folder: Screening

Form: Medical History (7)

Data signed: ▨ (b) (4) ▨ **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	28 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3642261

Folder: Screening

Form: Medical History (8)

Data signed: ███ (b) (4) ███ **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	TROCHANTERIC BURSITIS OF BOTH HIPS
Start date (dd MMM yyyy)	28 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	21 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	SACROILIAL JOINT DYSFUNCTION
Start date (dd MMM yyyy)	28 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	21 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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EAB) (1725)

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	CIGARETTE SMOKER
Start date (dd MMM yyyy)	22 APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3642261

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	19 SEP 2020
Time of assessment *(00:00-23:59)*	13:11 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 13:11
Height *(xxx.x)*	156.2 cm
Weight *(xxx.x)*	66.6 kg
BMI *(xxx.x)*	27.29683 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was the physical examination performed?   Yes ●

                                                                                 No ○

Date of examination *(dd MMM yyyy)*   19 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 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Date of assessment *(dd MMM yyyy)*	19 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)*	UN UNK 1992
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

Folder: Screening

Form: Risk of Exposure

Data signed: ▓▓ (b) (4) ▓▓ **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ● No ○
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ○ No ●
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ○ No ●
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ○ No ●
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ○ No ●
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ○ No ●
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ○ No ●
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ○ No ●
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ○ No ●
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ○ No ●
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ○ No ●
Other	Yes ○ No ●

　Specify _____

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **13 Feb 2021 18:28:35**

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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)	True
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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	19 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **13 Feb 2021 18:28:35**

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What was the date of randomization? *(dd MMM yyyy)*	19 SEP 2020
What was the participant's randomization number?	191228

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 18:28:35**

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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 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	19 SEP 2020
Time of assessment *(00:00-23:59)*	13:11 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 13:11
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	51 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	57 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 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	19 SEP 2020
Time of assessment *(00:00-23:59)*	15:54 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 15:54
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 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 18:28:35**

Generated On: 11 Aug 2021 22:57:45

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.

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)*	19 SEP 2020
What was the treatment time? *(00:00-23:59)*	15:11 (24 HR)
Treatment Date and Time (derived)	19 SEP 2020 15:11
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

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Feb 2021 18:28:35**

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Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	19 SEP 2020
Collection time *(00:00-23:59)*	14:50 (24 HR)
Collection date and time (derived)	19 SEP 2020 14:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Collection date *(dd MMM yyyy)*			19 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:25	19 SEP 2020 14:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4)   **13 Feb 2021 18:28:35**

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Is the participant continuing to the next visit?   Yes ●

                                                                No ○

Continuing Flag   1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °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	19 SEP 2020 15:48
PC Open Date & Time	19 SEP 2020 15:31
PC Close Date & Time	19 SEP 2020 18:01

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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	19 SEP 2020 19:08
PC Open Date & Time	19 SEP 2020 18:56
PC Close Date & Time	20 SEP 2020 11:59

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.7 °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	20 SEP 2020 20:37
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:45

DAY 3

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

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

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

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

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

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

| Was **TEMPERATURE** taken? | Yes ● |
| | No ○ |

| Please record your **TEMPERATURE in °F** | 98.3 °F |

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

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

PC Time Stamp	21 SEP 2020 17:26
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-2899262

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 SEP 2020 17:48
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ◯
	No ◯
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.6 °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	24 SEP 2020 18:55
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

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

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

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

PC Time Stamp	25 SEP 2020 20:56
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

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	19 SEP 2020 15:49
PC Open Date & Time	19 SEP 2020 15:31
PC Close Date & Time	19 SEP 2020 18:01

FDA-CBER-2022-1614-2899267

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

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	19 SEP 2020 19:09
PC Open Date & Time	19 SEP 2020 18:56
PC Close Date & Time	20 SEP 2020 11:59

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	20 SEP 2020 20:38
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:45

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	21 SEP 2020 17:26
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:45

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	22 SEP 2020 17:48
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:45

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 ◯
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	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:45

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	24 SEP 2020 18:55
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:45

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	25 SEP 2020 20:56
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:57:45

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 ○

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○

PC Time stamp	19 SEP 2020 15:49
PC Open Date & Time	19 SEP 2020 15:31
PC Close Date & Time	19 SEP 2020 18:01

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

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	○

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○

PC Time stamp	19 SEP 2020 19:09
PC Open Date & Time	19 SEP 2020 18:56
PC Close Date & Time	20 SEP 2020 11:59

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:57:45

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 ●

	Yes ◯
PC Time stamp	20 SEP 2020 20:38
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:45

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 ⬤

	Yes ◯
PC Time stamp	21 SEP 2020 17:27
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:57:45

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 ●

	Yes ◯
PC Time stamp	22 SEP 2020 17:49
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:45

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 ◯

	Yes ◯
PC Time stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:57:45

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 ●

	Yes ◯
PC Time stamp	24 SEP 2020 18:55
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

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 ●

	Yes ◯
PC Time stamp	25 SEP 2020 20:57
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3642261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 28 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3642261

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?   Yes ●

                                                     No ○

Continuing Flag   1

US3642261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3642261

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3642261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 13 OCT 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3642261

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?   Yes ●

                                                                                                                     No ○

Continuing Flag   1

US3642261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was this visit performed?   Yes ●

                                                                                    No ◯

Visit date (dd MMM yyyy)   17 OCT 2020

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

                                                                                  Clinic ●

Folder OID   VISIT2

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	17 OCT 2020
Time of assessment *(00:00-23:59)*	12:48 (24 HR)
Vital Signs Date and Time (derived)	17 OCT 2020 12:48
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	55 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
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	

US3642261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was the physical examination performed?   Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)*   17 OCT 2020

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

US3642261
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) 20 Oct 2020 22:38:33
Generated On: 11 Aug 2021 22:57:45

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   SUBJECT EXPERIENCING NEW
Participant, Protocol Deviation, or Other, specify   PARESTHESIAS AND
                                                             DECREASED SENSATION IN
                                                          HER TOES AND BALL OF BOTH
                                                           FEET L>R. S/P HISTORY OF
                                                          LAMINECTOMY IN JAN 2020.

What was the study treatment?   _____
What was the treatment date? *(dd MMM yyyy)*   _____
What was the treatment time? *(00:00-23:59)*   _____
Treatment Date and Time (derived)   _____
Which arm was used to give treatment?   Left Arm ◯
                                                                  Right Arm ◯

What was the frequency of the study treatment dosing?   _____
What was the route of administration for the study treatment?   _____

US3642261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	17 OCT 2020
Collection time *(00:00-23:59)*	14:32 (24 HR)
Collection date and time (derived)	17 OCT 2020 14:32

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Collection date *(dd MMM yyyy)*			17 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:34	17 OCT 2020 14:34
Nasopharyngeal Swab 2	No		

US3642261

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3642261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

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   _____

US3642261

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?　　　　　　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3642261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

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

US3642261

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3642261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

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   _____

US3642261

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3642261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was this visit performed?   Yes ◯

                                                                                         No ⬤

Visit date (dd MMM yyyy)

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

                                                                                         Clinic ◯

Folder OID   VISIT3

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) _____

US3642261

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4)   **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

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.

US3642261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Was the sample collected?   Yes ◯

No ⬤

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

US3642261

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?   Yes ●

                                                                No ○

Continuing Flag   1

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 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 ⃝

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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 ≥ 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 ◯

FDA-CBER-2022-1614-2899318

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

FDA-CBER-2022-1614-2899320

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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 ◯
Yes ◯

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

No ◯
Yes ◯

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

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 ◯ |
| | Yes ◯ |

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

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

| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯ |

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

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 ≥ 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 ◯

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

US3642261

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:57:45

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

US3642261
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 18:28:35**
Generated On: 11 Aug 2021 22:57:45

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 DEC 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3642261

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3642261
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45

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 _____

Is the participant continuing to the next visit?   Yes ⬭

No ⬭

Continuing Flag

US3642261
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:57:45

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ⬭
	Clinical Visit - Unscheduled ⬭
	Safety Call ⬭
	Convalescent Tele-visit ⬭
Has the subject reported symptoms of SARS-COV-2?	Yes ⬭
	No ⬭

US3642261
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:57:45

| Generate Next COVID-19 Assessment | Yes ◯ |
| | No ◯ |

Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4)   **03 Apr 2021 23:34:00**
Generated On: 11 Aug 2021 22:57:45

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ●
	Amendment 6 or later ○
Date of unblinding *(dd MMM yyyy)*	26 DEC 2020
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ○
	Not Administered ●
Will participant receive mRNA-1273?	Yes ○
	No ●
Placebo Only Flag	1
Continuing with mRNA-1273	

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US3642261

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **13 Feb 2021 18:28:34**

Generated On: 11 Aug 2021 22:57:45

Did the participant experience any adverse events?   Yes ⬤

No ◯

If Yes, enter details on the Adverse Events form.

US3642261

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **13 Feb 2021 18:28:34**

Generated On: 11 Aug 2021 22:57:45

AEID	
Adverse event	DECREASE IN SENSATION AND PARESTHESIA
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)*	03 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)*	
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	
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

FDA-CBER-2022-1614-2899338

US3642261

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **13 Feb 2021 18:28:34**

Generated On: 11 Aug 2021 22:57:45

SUBJECT REPORTS DECREASE
IN SENSATION AND
PARESTHESIAS.
VACCINE #2 INVESTIGATIONAL
PRODUCT NOT GIVEN. SUBJECT
DIAGNOSED WITH SOFT TISSUE
BUNIONETTE BY PRIMARY
CARE PHYSICIAN. SUBJECT
WILL CONTINUE TO REMAIN
ON STUDY.

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

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

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

                                                                            No ○

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

Name of Medication	FLU VACCINE

Prophylaxis	Yes ●
	No ○

Indication	PROPHYLAXIS FOR FLU
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)

Intramuscular	⬤
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	01 SEP 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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **09 Apr 2021 00:00:51**

Generated On: 11 Aug 2021 22:57:45

Name of Medication	MULTI VITAMIN
Prophylaxis	Yes ●
	No ○
Indication	SUPPLEMENT
Dose per administration	1
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ●
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	02 AUG 2019
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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

FDA-CBER-2022-1614-2899344

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4)   **09 Apr 2021 00:00:51**

Generated On: 11 Aug 2021 22:57:45

Name of Medication	VITAMIN D3

Prophylaxis	Yes ◯
	No ⬤

Indication	VITAMIN D DEFICIENCY
Dose per administration	5000

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 ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JUL 2019
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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Name of Medication	RED RICE YEAST

Prophylaxis	Yes ●
	No ○

Indication	SUPPLEMENT FOR HIGH CHOLESTEROL

Dose per administration	1

Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ●
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

FDA-CBER-2022-1614-2899347

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)*	UN JUL 2019
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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

FDA-CBER-2022-1614-2899348

Name of Medication	NAPROXEN

Prophylaxis	Yes ○
	No ●

Indication	BACK PAIN

Dose per administration	500

Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	_____

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

If frequency is Other, specify	_____

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

FDA-CBER-2022-1614-2899349

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*   UN UNK 2017

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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **09 Apr 2021 00:00:51**

Generated On: 11 Aug 2021 22:57:45

Name of Medication	FUROSEMIDE

Prophylaxis

Yes ⚪
No ⚫

Indication	DEPENDENT EDEMA
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 ⚪

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	23 FEB 2019
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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **09 Apr 2021 00:00:51**

Generated On: 11 Aug 2021 22:57:45

Name of Medication	METHYLPREDNISOLONE (MEDROL DOSEPACK)
Prophylaxis	Yes ○ No ●
Indication	DECREASE IN SENSATION AND PARESTHESIA
Dose per administration	4
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	◯
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)*	18 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **09 Apr 2021 00:00:51**

Generated On: 11 Aug 2021 22:57:45

Name of Medication	CHANTIX
Prophylaxis	Yes ⚪
	No ⚫
Indication	CIGARETTE SMOKER
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 ⚪

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Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 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 ◯

Name of Medication	MODERNA COVID-19 VACCINE (EXTERNAL)

Prophylaxis	Yes ●
	No ○

Indication	COVID-19 PROPHYLAXIS

Dose per administration	0.5

Dose unit	mg ○
	ug ○
	mL ●
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○

Intraocular ◯

Intramuscular ⬤

Respiratory (Inhalation) ◯

Intralesional ◯

Intraperiteoneal ◯

Nasal ◯

Vaginal ◯

Rectal ◯

Intravenous ◯

Intravenous Bolus ◯

Intravenous Drip ◯

Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	27 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	27 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 ◯

US3642261

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **13 Feb 2021 18:28:35**

Generated On: 11 Aug 2021 22:57:45

Were any concomitant procedures performed?   Yes ◯

                                                                                 No ⬤

If yes, please complete Concomitant Procedures form.

US3642261

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) **13 Mar 2021 02:23:27**

Generated On: 11 Aug 2021 22:57:45

Date of dosing discontinuation (dd MMM yyyy)	17 OCT 2020

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	AE # 1

US3642261

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) **09 Apr 2021 00:00:51**

Generated On: 11 Aug 2021 22:57:45

Date of study discontinuation/completion *(dd MMM yyyy)*	27 DEC 2020

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	PARTICIPANT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY THROUGH EUA

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

US3642261 (Prod: University of California San Diego)

US3642261
Form: Participant Creation
Generated On: 11 Aug 2021 22:57:45
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'US3642261'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 20:59:07

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 15:50:44
Query 'Per CDM: Please complete all applicable forms for this visit.' answered with 'forms completed' (Site from DM).	Benjamin Hull (b) (4) (b) (4)	01 Feb 2021 19:43:18
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:31
User opened query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:15:46
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:06

US3642261

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:45:31
User entered '19 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 20:59:08

US3642261

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:31
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:06

US3642261
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:57:45
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'SCRN'	System	19 Sep 2020 21:02:06

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 20:59:09

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '70'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:24

US3642261
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:57:45
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'YEARS'	System	19 Sep 2020 21:02:24

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '70'	System	19 Sep 2020 21:02:41

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered 'Female (F)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:24

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Megan Loughran (b) (4)	19 Sep 2020 21:02:24
	(b) (4)	

US3642261
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:57:45
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '1'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:24

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '0'	Megan Loughran (b) (4)	19 Sep 2020 21:02:24
	(b) (4)	

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '0'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:24

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '0'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:24

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '0'	Megan Loughran (b) (4)	19 Sep 2020 21:02:24

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '0'	Megan Loughran (b) (4)	19 Sep 2020 21:02:24

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered empty.	Megan Loughran (b) (4)	19 Sep 2020 21:02:24

US3642261
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:57:45
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '0'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:24

US3642261

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:45

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:25
User entered '0'	Megan Loughran (b) (4)	19 Sep 2020 21:02:24
	(b) (4)	

US3642261

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:45

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:40
User entered '19 Sep 2020'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:41

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Sep 2020'	System	19 Sep 2020 21:02:41

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:45

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2020'	System	19 Sep 2020 21:02:41

US3642261

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:45

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:40
User entered 'Amendment 3 (3)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:41

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:40
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:41

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:40
User entered empty.	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:41

US3642261

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:40
User entered empty.	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:41

US3642261
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:57:45

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:45:40
User entered 'No (N)'	Megan Loughran (b) (4)	19 Sep 2020 21:02:41
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:45

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:45:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 20:59:08

US3642261
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:57:45
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	19 Sep 2020 21:02:51

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:57:45

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:46:08
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:02:51

Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:57:45
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:46:31
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:53:56

US3642261
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:57:45
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Gravitational oedema, LLT: Dependent edema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:43:39
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 09:43:39
Data point term sent to Coder	System	16 Oct 2020 21:00:06
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 20:59:28
User entered 'dependent edema' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 20:59:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 17:56:56
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 17:56:56
Data point term sent to Coder	System	01 Oct 2020 17:55:21
User entered 'constipation'	Son Do (b) (4)	01 Oct 2020 17:54:24

US3642261

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User closed query 'Reconcile Start date.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:47:29
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
Query 'Reconcile Start date.' answered with 'data in edc are correct. duplicate with incorrect start date has been removed from source. ' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:36:14
User opened query 'Reconcile Start date.' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 23:47:46
User entered 'UN UNK 2005' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 20:59:28
User entered '22 Apr 2020'	Son Do (b) (4)	01 Oct 2020 17:54:24

US3642261

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:54:24

US3642261

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:54:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	(b) (4) Son Do (b) (4)	01 Oct 2020 17:54:24

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:54:24

US3642261

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Jan 2005'	System	16 Oct 2020 20:59:28
User entered 'Apr 2020'	System	01 Oct 2020 17:54:24

US3642261

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2005'	System	16 Oct 2020 20:59:28
User entered '2020'	System	01 Oct 2020 17:54:24

US3642261

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:54:24

US3642261

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:54:24

US3642261
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:57:45
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:43:40
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 09:43:40
Data point term sent to Coder	System	16 Oct 2020 21:00:07
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 20:59:58
User entered 'vitamin d deficiency' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 20:59:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Lumbar spinal stenosis, LLT: Spinal stenosis of lumbar region - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:02:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:02:39
Data point term sent to Coder	System	01 Oct 2020 17:55:22
User entered 'spinal stenosisi of lumbar region'	Son Do (b) (4)	01 Oct 2020 17:54:47

US3642261
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:57:45
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:48:07
User entered 'UN Jul 2019' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 20:59:58
User entered '23 Sep 2019'	Son Do (b) (4)	01 Oct 2020 17:54:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:54:47

US3642261

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:54:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:54:47

US3642261
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:57:45
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4) (b) (4)	01 Oct 2020 17:54:47

US3642261

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Jul 2019'	System	16 Oct 2020 20:59:58
User entered 'Sep 2019'	System	01 Oct 2020 17:54:47

US3642261

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2019'	System	01 Oct 2020 17:54:47

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:54:47

US3642261

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:54:47

US3642261
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:57:45
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:43:44
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 09:43:44
Data point term sent to Coder	System	16 Oct 2020 21:01:10
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:23
User entered 'post menopausal' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 17:56:58
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 17:56:58
Data point term sent to Coder	System	01 Oct 2020 17:55:23
User entered 'osteoporosis'	Son Do (b) (4)	01 Oct 2020 17:55:04

US3642261
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:23
User entered '28 Oct 2019'	Son Do (b) (4)	01 Oct 2020 17:55:04

US3642261

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:48:26
User entered '1' reason for change: Data Entry Error	Megan Loughran (b) (4)	16 Oct 2020 21:00:23
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:55:04

US3642261

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:55:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:55:04

US3642261

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	(b) (4) Son Do (b) (4)	01 Oct 2020 17:55:04

US3642261

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	16 Oct 2020 21:00:23
User entered 'Oct 2019'	System	01 Oct 2020 17:55:04

US3642261

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	16 Oct 2020 21:00:23
User entered '2019'	System	01 Oct 2020 17:55:04

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:55:04

US3642261

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:55:04

US3642261
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:57:45
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:00:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:00:04
Data point term sent to Coder	System	18 Dec 2020 20:59:12
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:56
User entered 'hysterectomy' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:56
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
Data point term sent to Coder	System	16 Oct 2020 21:01:10
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Trochanteric syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 08:56:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 08:56:53
Data point term sent to Coder	System	01 Oct 2020 17:56:25
User entered 'trochanteric'	Son Do (b) (4)	01 Oct 2020 17:55:26

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'UN UNK 1992' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:56
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered '28 Oct 2019'	Son Do (b) (4)	01 Oct 2020 17:55:26

US3642261

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:55:26

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:56
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:55:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'un UNK 1992' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:56
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:55:26

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:55:26

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Jan 1992'	System	18 Dec 2020 20:58:56
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered 'Oct 2019'	System	01 Oct 2020 17:55:26

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1992'	System	18 Dec 2020 20:58:56
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered '2019'	System	01 Oct 2020 17:55:26

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Jan 1992'	System	18 Dec 2020 20:58:56
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered empty.	System	01 Oct 2020 17:55:26

US3642261

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1992'	System	18 Dec 2020 20:58:56
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:22
DataPoint inactivated with code reason code Data not required.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:00:46
User entered empty.	System	01 Oct 2020 17:55:26

US3642261

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:07:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:07:40
Data point term sent to Coder	System	18 Dec 2020 21:06:17
User entered 'constipation'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:05:45

US3642261
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:57:45
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:49:02
User entered '22 Apr 2020'	Megan Loughran (b) (4)	18 Dec 2020 21:05:45
	(b) (4)	

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:05:45

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:05:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:05:45

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:05:45

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Apr 2020'	System	18 Dec 2020 21:05:45

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2020'	System	18 Dec 2020 21:05:45

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:05:45

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:05:45

US3642261

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Lumbar spinal stenosis, LLT: Lumbar spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:27
Data point term sent to Coder	System	18 Dec 2020 21:06:17
User entered 'spinal stenosis of lumbar region with radiculopathy'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:04

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:49:11
User entered '23 Sep 2019'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:04

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:04

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:04

US3642261

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:04

US3642261

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:04

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Sep 2019'	System	18 Dec 2020 21:06:04

US3642261

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2019'	System	18 Dec 2020 21:06:04

US3642261

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:06:04

US3642261

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:06:04

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:07:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:07:41
Data point term sent to Coder	System	18 Dec 2020 21:07:18
User entered 'osteoporosis'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:20

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:49:20
User entered '28 Oct 2019'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Oct 2019'	System	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2019'	System	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:06:20

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Trochanteric bursitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Dec 2020 20:47:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Dec 2020 20:47:42
Data point term sent to Coder	System	18 Dec 2020 21:07:19
User entered 'trochanteric bursitis of both hips'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User closed query 'verify start date and end date per source please. ' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:48:05
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
Query 'verify start date and end date per source please. ' answered with 'source verified; edc updated. ' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:37:53
User opened query 'verify start date and end date per source please. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 23:50:22
User entered '28 Oct 2019'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:39

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:37:41
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '21 Jan 2020' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:37:41
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Oct 2019'	System	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2019'	System	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Jan 2020'	System	09 Feb 2021 21:37:41
User entered empty.	System	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2020'	System	09 Feb 2021 21:37:41
User entered empty.	System	18 Dec 2020 21:06:39

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthropathy, LLT: Joint dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:06
Data point term sent to Coder	System	18 Dec 2020 21:07:19
User entered 'sacroilial joint dysfunction'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:55

FDA-CBER-2022-1614-2899476

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User closed query 'reconcile entry per source please. ' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:48:38
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
Query 'reconcile entry per source please. ' answered with 'source verified; edc updated. ' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:38:21
User opened query 'reconcile entry per source please. ' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 23:50:59
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	18 Dec 2020 21:07:07
User entered '28 Oct 2019' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:07:07
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	18 Dec 2020 21:06:55
User entered '28 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:55

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:55

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:38:17
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:55

FDA-CBER-2022-1614-2899479

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '21 Jan 2020' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:38:17
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:55

FDA-CBER-2022-1614-2899480

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:06:55

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Oct 2019'	System	18 Dec 2020 21:07:07
User entered 'Oct 2020'	System	18 Dec 2020 21:06:55

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2019'	System	18 Dec 2020 21:07:07
User entered '2020'	System	18 Dec 2020 21:06:55

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Jan 2020'	System	09 Feb 2021 21:38:17
User entered empty.	System	18 Dec 2020 21:06:55

US3642261

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2020'	System	09 Feb 2021 21:38:17
User entered empty.	System	18 Dec 2020 21:06:55

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per MM: Please clarify MH term.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:36:36
Query 'Per MM: Please clarify MH term.' answered with 'participant is a cigarette smoker. This is the diagnosis as recorded in medical record. Participant takes medications for smoking cessation, so this condition is recorded in mh as it is documented in her medical record. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:39:27
User opened query 'Per MM: Please clarify MH term.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 19:00:54
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Cigarette smoker - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:08:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:08:41
Data point term sent to Coder	System	18 Dec 2020 21:08:21
User entered 'cigarette smoker'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:51:10
User entered '22 Apr 2020'	Megan Loughran (b) (4)	18 Dec 2020 21:07:23
	(b) (4)	

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Apr 2020'	System	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2020'	System	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:07:23

US3642261

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 21:34:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 21:34:37
Data point term sent to Coder	System	09 Feb 2021 21:33:40
User entered 'back pain'	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:33:18

US3642261

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'un UNK 2017'	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:33:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:33:18

US3642261

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:33:18

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:33:18

US3642261

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:33:18

US3642261

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'Jan 2017'	System	09 Feb 2021 21:33:18

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '2017'	System	09 Feb 2021 21:33:18

US3642261

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	09 Feb 2021 21:33:18

US3642261

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	09 Feb 2021 21:33:18

US3642261

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:57:43

US3642261

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered '19 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:57:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered '13:11'	Son Do (b) (4)	01 Oct 2020 17:57:43

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '19 Sep 2020 13:11'	System	01 Oct 2020 17:57:43

US3642261
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered '156.2' cm	Son Do (b) (4)	01 Oct 2020 17:57:43
DataPoint set to visible.	System	19 Sep 2020 21:02:51

Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered '66.6' kg	Son Do (b) (4)	01 Oct 2020 17:57:43
DataPoint set to visible.	System	19 Sep 2020 21:02:51

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '27.29683'	System	01 Oct 2020 17:57:43
DataPoint set to visible.	System	19 Sep 2020 21:02:51

US3642261

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'kg/m2'	System	01 Oct 2020 17:57:43
DataPoint set to visible.	System	19 Sep 2020 21:02:51

US3642261

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:57:43

US3642261

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:57:43

US3642261
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:57:43

US3642261
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:57:43

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'bpm'	System	01 Oct 2020 17:57:43

US3642261
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:57:43

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'breaths/min'	System	01 Oct 2020 17:57:43

US3642261

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:57:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'mmHg'	System	01 Oct 2020 17:57:43

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:47
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:57:43

US3642261

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'mmHg'	System	01 Oct 2020 17:57:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

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Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:45

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:52
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:57:09

US3642261

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:45

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:51:52
User entered '19 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:57:09

US3642261

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:45

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:05
User entered '19 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:59:09

US3642261

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:45

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:05
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:09

US3642261

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:45

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:52:05
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	18 Dec 2020 20:59:23
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	18 Dec 2020 20:59:16
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 20:59:16
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Son Do (b) (4)	01 Oct 2020 17:59:09

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:45

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:05
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:59:09

US3642261

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:52:05
User entered 'un UNK 1992' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:59:16
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:59:09

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:45

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:05
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:59:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:05
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:59:09

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Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:57:45
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:05
User entered '0' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 20:59:23
User entered '1'	Son Do (b) (4) (b) (4)	01 Oct 2020 17:59:09

US3642261

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:59:37

US3642261
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:57:45
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	(b) (4) Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:59:37

US3642261

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered '1'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:59:37

US3642261

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:59:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:59:37

US3642261
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:57:45
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:52:27
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:59:37

US3642261

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:23
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:03:00

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:23
User entered '19 Sep 2020'	Megan Loughran (b) (4)	19 Sep 2020 21:03:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:23
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4)	19 Sep 2020 21:03:00
	(b) (4)	

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Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:57:45
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'VISIT1'	System	19 Sep 2020 21:03:00

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:45

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered '19 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 21:04:08

US3642261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:45

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered '191228'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 21:04:08

US3642261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:45

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 21:04:08

US3642261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered 'No (N)'	Megan Loughran (b) (4)	19 Sep 2020 21:03:20

US3642261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:03:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:45

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:03:20

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:03:20

FDA-CBER-2022-1614-2899568

US3642261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:45

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:03:20

FDA-CBER-2022-1614-2899569

US3642261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:45

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:31
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 21:03:20
DataPoint set to visible.	System	19 Sep 2020 21:02:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:58:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '19 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '13:11'	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '19 Sep 2020 13:11'	System	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '98.1' F	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered 'Oral (Oral)'	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '51'	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:57:45
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'bpm'	System	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '16'	Son Do (b) (4)	01 Oct 2020 17:58:26

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'breaths/min'	System	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '115'	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'mmHg'	System	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 03:58:26
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NOT CLINICALLY SIGNIFICANT ' (Site from System).	Colleen McLellan (b) (4) (b) (4)	17 Nov 2020 16:28:29
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Oct 2020 17:58:26
User entered '57'	Son Do (b) (4)	01 Oct 2020 17:58:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'mmHg'	System	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered missing code ND - Not Done.	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '19 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User closed query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 15:11, but time of Assessment is 13:54 (-77 minutes). Please review and update or provide a clarification. Thank you' (Site from DM).		18 Nov 2020 03:44:25
Query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 15:11, but time of Assessment is 13:54 (-77 minutes). Please review and update or provide a clarification. Thank you' answered with 'POST-DOSE VS TIME CORRECTED - 1554' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	17 Nov 2020 16:30:50
User entered '15:54' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	17 Nov 2020 16:30:04
User opened query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 15:11, but time of Assessment is 13:54 (-77 minutes). Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 22:21:06
User entered '13:54'	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '19 Sep 2020 15:54'	System	17 Nov 2020 16:30:04
User entered '19 Sep 2020 13:54'	System	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '98.7' F	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered 'Oral (Oral)'	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '59'	Son Do (b) (4)	01 Oct 2020 17:58:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'bpm'	System	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '16'	Son Do (b) (4)	01 Oct 2020 17:58:26

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'breaths/min'	System	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '126'	Son Do (b) (4)	01 Oct 2020 17:58:26

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'mmHg'	System	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:01:06
User entered '60'	Son Do (b) (4)	01 Oct 2020 17:58:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'mmHg'	System	01 Oct 2020 17:58:26

US3642261

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:45

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:16
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 20:58:09
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:57:18

FDA-CBER-2022-1614-2899609

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:45

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:16
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 20:58:09
User entered '19 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:57:18

US3642261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:45

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:24
User entered 'Yes (Y)'	Megan Loughran (b) (4)	19 Sep 2020 22:14:56

US3642261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:45

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:24
User entered empty.	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 22:14:56

US3642261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:24
User entered empty.	Megan Loughran (b) (4)	19 Sep 2020 22:14:56

US3642261
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:57:45

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'MRNA-1273 OR PLACEBO'	System	19 Sep 2020 22:14:56

US3642261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:45

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:24
User entered '19 Sep 2020'	Megan Loughran (b) (4)	19 Sep 2020 22:14:56

US3642261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:24
User entered '15:11'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 22:14:56

US3642261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:45

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '19 Sep 2020 15:11'	System	19 Sep 2020 22:14:56

US3642261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:45

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:01:24
User entered 'Left Arm (LEFT ARM)'	Megan Loughran (b) (4) (b) (4)	19 Sep 2020 22:14:56

US3642261
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:57:45
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint Verified.		19 Dec 2020 00:01:24
User entered 'ONCE'	System	19 Sep 2020 22:14:56

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:57:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'INTRAMUSCULAR'	System	19 Sep 2020 22:14:56

US3642261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:45

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:02:05
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:58:40

US3642261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:45

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:05
User entered '19 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:58:40

US3642261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:02:05
User entered '14:50'	Son Do (b) (4)	01 Oct 2020 17:58:40

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '19 Sep 2020 14:50'	System	01 Oct 2020 17:58:40

US3642261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:57:45

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:17
User entered '19 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:58:53

US3642261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:45

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	01 Oct 2020 17:58:53

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:57:45

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:17
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:58:53

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US3642261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:17
User entered '14:25'	Son Do (b) (4)	01 Oct 2020 17:58:53

US3642261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:45

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '19 Sep 2020 14:25'	System	01 Oct 2020 17:58:53

US3642261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:45

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Son Do (b) (4)	01 Oct 2020 17:58:53

US3642261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:45

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:17
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:58:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:17
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:58:53

FDA-CBER-2022-1614-2899632

US3642261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:45

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:58:53

US3642261

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:23
User entered 'Yes (Y)'	Nancy Tang (b) (4)	28 Sep 2020 19:55:20

US3642261
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:57:45
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	28 Sep 2020 19:55:20

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:47:41', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'cf69051d-cd71-43c2-ad9f-fef3895bc848'	System	19 Sep 2020 22:48:07
User entered 'Yes (Y)'	System	19 Sep 2020 22:48:07

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:47:55', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'cf69051d-cd71-43c2-ad9f-fef3895bc848'	System	19 Sep 2020 22:48:07
User entered '97.7'	System	19 Sep 2020 22:48:07

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:47:59', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'cf69051d-cd71-43c2-ad9f-fef3895bc848'	System	19 Sep 2020 22:48:07
User entered 'No (N)'	System	19 Sep 2020 22:48:07

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:48:04', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'cf69051d-cd71-43c2-ad9f-fef3895bc848'	System	19 Sep 2020 22:48:07
User entered '19 Sep 2020 15:48'	System	19 Sep 2020 22:48:07

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 15:31'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 18:01'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:08:27', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8eae519e-05d6-4359-9520-1e810010cf0c'	System	20 Sep 2020 02:08:50
User entered 'Yes (Y)'	System	20 Sep 2020 02:08:50

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:08:33', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8eae519e-05d6-4359-9520-1e810010cf0c'	System	20 Sep 2020 02:08:50
User entered '98.1'	System	20 Sep 2020 02:08:50

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:08:37', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8eae519e-05d6-4359-9520-1e810010cf0c'	System	20 Sep 2020 02:08:50
User entered 'No (N)'	System	20 Sep 2020 02:08:50

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US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:08:47', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8eae519e-05d6-4359-9520-1e810010cf0c'	System	20 Sep 2020 02:08:50
User entered '19 Sep 2020 19:08'	System	20 Sep 2020 02:08:50

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 18:56'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 2'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:37:27', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '7e930bb8-3ecc-44bc-8ec2-0d48b4afa7fd'	System	21 Sep 2020 03:37:44
User entered 'Yes (Y)'	System	21 Sep 2020 03:37:44

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:37:33', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '7e930bb8-3ecc-44bc-8ec2-0d48b4afa7fd'	System	21 Sep 2020 03:37:44
User entered '98.7'	System	21 Sep 2020 03:37:44

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:37:37', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '7e930bb8-3ecc-44bc-8ec2-0d48b4afa7fd'	System	21 Sep 2020 03:37:44
User entered 'No (N)'	System	21 Sep 2020 03:37:44

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:57:45
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:37:42', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '7e930bb8-3ecc-44bc-8ec2-0d48b4afa7fd'	System	21 Sep 2020 03:37:44
User entered '20 Sep 2020 20:37'	System	21 Sep 2020 03:37:44

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 3'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:25:44', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fd928703-2d5a-4c00-a808-d531333a9762'	System	22 Sep 2020 00:26:04
User entered 'Yes (Y)'	System	22 Sep 2020 00:26:04

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:25:50', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fd928703-2d5a-4c00-a808-d531333a9762'	System	22 Sep 2020 00:26:04
User entered '98.3'	System	22 Sep 2020 00:26:04

FDA-CBER-2022-1614-2899659

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:25:53', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fd928703-2d5a-4c00-a808-d531333a9762'	System	22 Sep 2020 00:26:04
User entered 'No (N)'	System	22 Sep 2020 00:26:04

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:57:45
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:02', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fd928703-2d5a-4c00-a808-d531333a9762'	System	22 Sep 2020 00:26:04
User entered '21 Sep 2020 17:26'	System	22 Sep 2020 00:26:04

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:57:45
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 4'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:47:58', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '4db4e159-00d4-42a9-9931-8fa06ef86ef8'	System	23 Sep 2020 00:48:16
User entered 'Yes (Y)'	System	23 Sep 2020 00:48:16

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:03', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '4db4e159-00d4-42a9-9931-8fa06ef86ef8'	System	23 Sep 2020 00:48:16
User entered '99.0'	System	23 Sep 2020 00:48:16

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:06', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '4db4e159-00d4-42a9-9931-8fa06ef86ef8'	System	23 Sep 2020 00:48:16
User entered 'No (N)'	System	23 Sep 2020 00:48:16

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US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:45

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:11', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '4db4e159-00d4-42a9-9931-8fa06ef86ef8'	System	23 Sep 2020 00:48:16
User entered '22 Sep 2020 17:48'	System	23 Sep 2020 00:48:16

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:57:45
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 5'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:57:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

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US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:45

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 6'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:57:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:54:41', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '6fb80a70-3a61-4ea2-a6ee-b5d2305d4530'	System	25 Sep 2020 01:55:08
User entered 'Yes (Y)'	System	25 Sep 2020 01:55:08

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:54:54', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '6fb80a70-3a61-4ea2-a6ee-b5d2305d4530'	System	25 Sep 2020 01:55:08
User entered '98.6'	System	25 Sep 2020 01:55:08

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:54:57', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '6fb80a70-3a61-4ea2-a6ee-b5d2305d4530'	System	25 Sep 2020 01:55:08
User entered 'No (N)'	System	25 Sep 2020 01:55:08

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:57:45
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:04', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '6fb80a70-3a61-4ea2-a6ee-b5d2305d4530'	System	25 Sep 2020 01:55:08
User entered '24 Sep 2020 18:55'	System	25 Sep 2020 01:55:08

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:57:45
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 7'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:08', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'c10f0722-fa22-45f4-881d-a26b2c5d3a2d'	System	26 Sep 2020 03:56:22
User entered 'Yes (Y)'	System	26 Sep 2020 03:56:22

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:14', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'c10f0722-fa22-45f4-881d-a26b2c5d3a2d'	System	26 Sep 2020 03:56:22
User entered '98.6'	System	26 Sep 2020 03:56:22

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:17', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'c10f0722-fa22-45f4-881d-a26b2c5d3a2d'	System	26 Sep 2020 03:56:22
User entered 'No (N)'	System	26 Sep 2020 03:56:22

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US3642261
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:57:45
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:21', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'c10f0722-fa22-45f4-881d-a26b2c5d3a2d'	System	26 Sep 2020 03:56:22
User entered '25 Sep 2020 20:56'	System	26 Sep 2020 03:56:22

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:48:19', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd5200364-a125-4417-ae28-c15f9df123a1'	System	19 Sep 2020 22:49:03
User entered 'None (1)'	System	19 Sep 2020 22:49:03

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:48:42', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd5200364-a125-4417-ae28-c15f9df123a1'	System	19 Sep 2020 22:49:03
User entered 'No (N)'	System	19 Sep 2020 22:49:03

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:48:47', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd5200364-a125-4417-ae28-c15f9df123a1'	System	19 Sep 2020 22:49:03
User entered 'No (N)'	System	19 Sep 2020 22:49:03

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:48:56', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd5200364-a125-4417-ae28-c15f9df123a1'	System	19 Sep 2020 22:49:03
User entered 'None (1)'	System	19 Sep 2020 22:49:03

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:01', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd5200364-a125-4417-ae28-c15f9df123a1'	System	19 Sep 2020 22:49:03
User entered '19 Sep 2020 15:49'	System	19 Sep 2020 22:49:03

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 15:31'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 18:01'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:08:54', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '9023ae7f-f8fe-4a20-93ee-4e4440804234'	System	20 Sep 2020 02:09:24
User entered 'None (1)'	System	20 Sep 2020 02:09:24

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:08:57', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '9023ae7f-f8fe-4a20-93ee-4e4440804234'	System	20 Sep 2020 02:09:24
User entered 'No (N)'	System	20 Sep 2020 02:09:24

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:08:59', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '9023ae7f-f8fe-4a20-93ee-4e4440804234'	System	20 Sep 2020 02:09:24
User entered 'No (N)'	System	20 Sep 2020 02:09:24

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:13', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '9023ae7f-f8fe-4a20-93ee-4e4440804234'	System	20 Sep 2020 02:09:24
User entered 'None (1)'	System	20 Sep 2020 02:09:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:21', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '9023ae7f-f8fe-4a20-93ee-4e4440804234'	System	20 Sep 2020 02:09:24
User entered '19 Sep 2020 19:09'	System	20 Sep 2020 02:09:24

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 18:56'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 2'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:37:56', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a211bc0a-f649-40a4-be7a-ac4ec3abe690'	System	21 Sep 2020 03:38:18
User entered 'None (1)'	System	21 Sep 2020 03:38:18

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:02', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a211bc0a-f649-40a4-be7a-ac4ec3abe690'	System	21 Sep 2020 03:38:18
User entered 'No (N)'	System	21 Sep 2020 03:38:18

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:06', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a211bc0a-f649-40a4-be7a-ac4ec3abe690'	System	21 Sep 2020 03:38:18
User entered 'No (N)'	System	21 Sep 2020 03:38:18

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:12', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a211bc0a-f649-40a4-be7a-ac4ec3abe690'	System	21 Sep 2020 03:38:18
User entered 'None (1)'	System	21 Sep 2020 03:38:18

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:45

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:16', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a211bc0a-f649-40a4-be7a-ac4ec3abe690'	System	21 Sep 2020 03:38:18
User entered '20 Sep 2020 20:38'	System	21 Sep 2020 03:38:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

FDA-CBER-2022-1614-2899716

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

FDA-CBER-2022-1614-2899717

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 3'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:06', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fdd7887d-774c-489b-abdd-9994ff8466be'	System	22 Sep 2020 00:26:40
User entered 'None (1)'	System	22 Sep 2020 00:26:40

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:18', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fdd7887d-774c-489b-abdd-9994ff8466be'	System	22 Sep 2020 00:26:40
User entered 'No (N)'	System	22 Sep 2020 00:26:40

FDA-CBER-2022-1614-2899720

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:24', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fdd7887d-774c-489b-abdd-9994ff8466be'	System	22 Sep 2020 00:26:40
User entered 'No (N)'	System	22 Sep 2020 00:26:40

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:33', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fdd7887d-774c-489b-abdd-9994ff8466be'	System	22 Sep 2020 00:26:40
User entered 'None (1)'	System	22 Sep 2020 00:26:40

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:57:45
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:36', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'fdd7887d-774c-489b-abdd-9994ff8466be'	System	22 Sep 2020 00:26:40
User entered '21 Sep 2020 17:26'	System	22 Sep 2020 00:26:40

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 4'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:20', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '57e6d30e-7f06-4549-9d3f-654751409513'	System	23 Sep 2020 00:48:44
User entered 'None (1)'	System	23 Sep 2020 00:48:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:23', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '57e6d30e-7f06-4549-9d3f-654751409513'	System	23 Sep 2020 00:48:44
User entered 'No (N)'	System	23 Sep 2020 00:48:44

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US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:28', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '57e6d30e-7f06-4549-9d3f-654751409513'	System	23 Sep 2020 00:48:44
User entered 'No (N)'	System	23 Sep 2020 00:48:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:35', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '57e6d30e-7f06-4549-9d3f-654751409513'	System	23 Sep 2020 00:48:44
User entered 'None (1)'	System	23 Sep 2020 00:48:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:45

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:39', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '57e6d30e-7f06-4549-9d3f-654751409513'	System	23 Sep 2020 00:48:44
User entered '22 Sep 2020 17:48'	System	23 Sep 2020 00:48:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 5'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

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US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:57:45
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 13:35:21

FDA-CBER-2022-1614-2899737

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:45

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:57:45
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 6'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:10', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8454c93e-8c6c-4c5b-b32c-b5b23639763c'	System	25 Sep 2020 01:55:26
User entered 'None (1)'	System	25 Sep 2020 01:55:26

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:13', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8454c93e-8c6c-4c5b-b32c-b5b23639763c'	System	25 Sep 2020 01:55:26
User entered 'No (N)'	System	25 Sep 2020 01:55:26

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:15', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8454c93e-8c6c-4c5b-b32c-b5b23639763c'	System	25 Sep 2020 01:55:26
User entered 'No (N)'	System	25 Sep 2020 01:55:26

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:21', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8454c93e-8c6c-4c5b-b32c-b5b23639763c'	System	25 Sep 2020 01:55:26
User entered 'None (1)'	System	25 Sep 2020 01:55:26

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:57:45
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:25', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '8454c93e-8c6c-4c5b-b32c-b5b23639763c'	System	25 Sep 2020 01:55:26
User entered '24 Sep 2020 18:55'	System	25 Sep 2020 01:55:26

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:57:45
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 7'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:26', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '87ff2f39-fc32-4fe6-8707-7f76aa7f55fd'	System	26 Sep 2020 03:56:44
User entered 'None (1)'	System	26 Sep 2020 03:56:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:28', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '87ff2f39-fc32-4fe6-8707-7f76aa7f55fd'	System	26 Sep 2020 03:56:44
User entered 'No (N)'	System	26 Sep 2020 03:56:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:31', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '87ff2f39-fc32-4fe6-8707-7f76aa7f55fd'	System	26 Sep 2020 03:56:44
User entered 'No (N)'	System	26 Sep 2020 03:56:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:36', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '87ff2f39-fc32-4fe6-8707-7f76aa7f55fd'	System	26 Sep 2020 03:56:44
User entered 'None (1)'	System	26 Sep 2020 03:56:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:45

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:38', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '87ff2f39-fc32-4fe6-8707-7f76aa7f55fd'	System	26 Sep 2020 03:56:44
User entered '25 Sep 2020 20:56'	System	26 Sep 2020 03:56:44

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:10', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '1adb560a-bb73-41db-a6d9-9a78f0d38dc1'	System	19 Sep 2020 22:49:52
User entered 'None (0)'	System	19 Sep 2020 22:49:52

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:14', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '1adb560a-bb73-41db-a6d9-9a78f0d38dc1'	System	19 Sep 2020 22:49:52
User entered 'None (0)'	System	19 Sep 2020 22:49:52

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:17', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '1adb560a-bb73-41db-a6d9-9a78f0d38dc1'	System	19 Sep 2020 22:49:52
User entered 'None (0)'	System	19 Sep 2020 22:49:52

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:20', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '1adb560a-bb73-41db-a6d9-9a78f0d38dc1'	System	19 Sep 2020 22:49:52
User entered 'None (0)'	System	19 Sep 2020 22:49:52

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:24', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '1adb560a-bb73-41db-a6d9-9a78f0d38dc1'	System	19 Sep 2020 22:49:52
User entered 'None (0)'	System	19 Sep 2020 22:49:52

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:57:45
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:27', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '1adb560a-bb73-41db-a6d9-9a78f0d38dc1'	System	19 Sep 2020 22:49:52
User entered 'None (0)'	System	19 Sep 2020 22:49:52

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:44', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '1adb560a-bb73-41db-a6d9-9a78f0d38dc1'	System	19 Sep 2020 22:49:52
User entered 'No (N)'	System	19 Sep 2020 22:49:52

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T15:49:48', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '1adb560a-bb73-41db-a6d9-9a78f0d38dc1'	System	19 Sep 2020 22:49:52
User entered '19 Sep 2020 15:49'	System	19 Sep 2020 22:49:52

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 15:31'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 18:01'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:57:45
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:31', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '717326fe-f23c-494b-9d51-d8c8ef5e1873'	System	20 Sep 2020 02:09:56
User entered 'None (0)'	System	20 Sep 2020 02:09:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:57:45
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:34', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '717326fe-f23c-494b-9d51-d8c8ef5e1873'	System	20 Sep 2020 02:09:56
User entered 'None (0)'	System	20 Sep 2020 02:09:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:36', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '717326fe-f23c-494b-9d51-d8c8ef5e1873'	System	20 Sep 2020 02:09:56
User entered 'None (0)'	System	20 Sep 2020 02:09:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:38', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '717326fe-f23c-494b-9d51-d8c8ef5e1873'	System	20 Sep 2020 02:09:56
User entered 'None (0)'	System	20 Sep 2020 02:09:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:57:45
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:41', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '717326fe-f23c-494b-9d51-d8c8ef5e1873'	System	20 Sep 2020 02:09:56
User entered 'None (0)'	System	20 Sep 2020 02:09:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:43', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '717326fe-f23c-494b-9d51-d8c8ef5e1873'	System	20 Sep 2020 02:09:56
User entered 'None (0)'	System	20 Sep 2020 02:09:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:48', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '717326fe-f23c-494b-9d51-d8c8ef5e1873'	System	20 Sep 2020 02:09:56
User entered 'No (N)'	System	20 Sep 2020 02:09:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-19T19:09:54', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '717326fe-f23c-494b-9d51-d8c8ef5e1873'	System	20 Sep 2020 02:09:56
User entered '19 Sep 2020 19:09'	System	20 Sep 2020 02:09:56

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '19 Sep 2020 18:56'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 2'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:57:45
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:23', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd4ac1a3a-328a-40c0-b992-50da4b0c5ace'	System	21 Sep 2020 03:38:48
User entered 'None (0)'	System	21 Sep 2020 03:38:48

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:57:45
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:25', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd4ac1a3a-328a-40c0-b992-50da4b0c5ace'	System	21 Sep 2020 03:38:48
User entered 'None (0)'	System	21 Sep 2020 03:38:48

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:29', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd4ac1a3a-328a-40c0-b992-50da4b0c5ace'	System	21 Sep 2020 03:38:48
User entered 'None (0)'	System	21 Sep 2020 03:38:48

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:32', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd4ac1a3a-328a-40c0-b992-50da4b0c5ace'	System	21 Sep 2020 03:38:48
User entered 'None (0)'	System	21 Sep 2020 03:38:48

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:57:45
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:35', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd4ac1a3a-328a-40c0-b992-50da4b0c5ace'	System	21 Sep 2020 03:38:48
User entered 'None (0)'	System	21 Sep 2020 03:38:48

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:37', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd4ac1a3a-328a-40c0-b992-50da4b0c5ace'	System	21 Sep 2020 03:38:48
User entered 'None (0)'	System	21 Sep 2020 03:38:48

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:41', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd4ac1a3a-328a-40c0-b992-50da4b0c5ace'	System	21 Sep 2020 03:38:48
User entered 'No (N)'	System	21 Sep 2020 03:38:48

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:45

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-20T20:38:46', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd4ac1a3a-328a-40c0-b992-50da4b0c5ace'	System	21 Sep 2020 03:38:48
User entered '20 Sep 2020 20:38'	System	21 Sep 2020 03:38:48

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 3'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:57:45
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:49', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd1932d76-562b-4ca8-89c0-cf503d1d845f'	System	22 Sep 2020 00:27:11
User entered 'None (0)'	System	22 Sep 2020 00:27:11

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:57:45
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:52', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd1932d76-562b-4ca8-89c0-cf503d1d845f'	System	22 Sep 2020 00:27:11
User entered 'None (0)'	System	22 Sep 2020 00:27:11

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:57:45
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:54', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd1932d76-562b-4ca8-89c0-cf503d1d845f'	System	22 Sep 2020 00:27:11
User entered 'None (0)'	System	22 Sep 2020 00:27:11

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:26:57', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd1932d76-562b-4ca8-89c0-cf503d1d845f'	System	22 Sep 2020 00:27:11
User entered 'None (0)'	System	22 Sep 2020 00:27:11

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:27:00', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd1932d76-562b-4ca8-89c0-cf503d1d845f'	System	22 Sep 2020 00:27:11
User entered 'None (0)'	System	22 Sep 2020 00:27:11

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:57:45
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:27:02', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd1932d76-562b-4ca8-89c0-cf503d1d845f'	System	22 Sep 2020 00:27:11
User entered 'None (0)'	System	22 Sep 2020 00:27:11

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:27:05', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd1932d76-562b-4ca8-89c0-cf503d1d845f'	System	22 Sep 2020 00:27:11
User entered 'No (N)'	System	22 Sep 2020 00:27:11

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:45

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-21T17:27:08', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'd1932d76-562b-4ca8-89c0-cf503d1d845f'	System	22 Sep 2020 00:27:11
User entered '21 Sep 2020 17:27'	System	22 Sep 2020 00:27:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

FDA-CBER-2022-1614-2899802

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 4'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:57:45
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:44', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '5794a8f9-1c34-4870-82b3-696a224cc81a'	System	23 Sep 2020 00:49:14
User entered 'None (0)'	System	23 Sep 2020 00:49:14

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:57:45
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:47', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '5794a8f9-1c34-4870-82b3-696a224cc81a'	System	23 Sep 2020 00:49:14
User entered 'None (0)'	System	23 Sep 2020 00:49:14

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:50', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '5794a8f9-1c34-4870-82b3-696a224cc81a'	System	23 Sep 2020 00:49:14
User entered 'None (0)'	System	23 Sep 2020 00:49:14

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:52', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '5794a8f9-1c34-4870-82b3-696a224cc81a'	System	23 Sep 2020 00:49:14
User entered 'None (0)'	System	23 Sep 2020 00:49:14

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:48:55', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '5794a8f9-1c34-4870-82b3-696a224cc81a'	System	23 Sep 2020 00:49:14
User entered 'None (0)'	System	23 Sep 2020 00:49:14

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:49:02', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '5794a8f9-1c34-4870-82b3-696a224cc81a'	System	23 Sep 2020 00:49:14
User entered 'No interference with activity (1)'	System	23 Sep 2020 00:49:14

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:49:05', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '5794a8f9-1c34-4870-82b3-696a224cc81a'	System	23 Sep 2020 00:49:14
User entered 'No (N)'	System	23 Sep 2020 00:49:14

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:45

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-22T17:49:09', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: '5794a8f9-1c34-4870-82b3-696a224cc81a'	System	23 Sep 2020 00:49:14
User entered '22 Sep 2020 17:49'	System	23 Sep 2020 00:49:14

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 5'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:57:45
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

FDA-CBER-2022-1614-2899816

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:57:45
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:57:45
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:57:45
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:45

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 6'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:33', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a4973499-8701-4288-9e17-e3af76ba640b'	System	25 Sep 2020 01:55:50
User entered 'None (0)'	System	25 Sep 2020 01:55:50

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:57:45
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:36', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a4973499-8701-4288-9e17-e3af76ba640b'	System	25 Sep 2020 01:55:50
User entered 'None (0)'	System	25 Sep 2020 01:55:50

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:37', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a4973499-8701-4288-9e17-e3af76ba640b'	System	25 Sep 2020 01:55:50
User entered 'None (0)'	System	25 Sep 2020 01:55:50

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:39', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a4973499-8701-4288-9e17-e3af76ba640b'	System	25 Sep 2020 01:55:50
User entered 'None (0)'	System	25 Sep 2020 01:55:50

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:57:45
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:41', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a4973499-8701-4288-9e17-e3af76ba640b'	System	25 Sep 2020 01:55:50
User entered 'None (0)'	System	25 Sep 2020 01:55:50

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:57:45
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:43', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a4973499-8701-4288-9e17-e3af76ba640b'	System	25 Sep 2020 01:55:50
User entered 'None (0)'	System	25 Sep 2020 01:55:50

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:46', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a4973499-8701-4288-9e17-e3af76ba640b'	System	25 Sep 2020 01:55:50
User entered 'No (N)'	System	25 Sep 2020 01:55:50

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:45

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-24T18:55:49', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a4973499-8701-4288-9e17-e3af76ba640b'	System	25 Sep 2020 01:55:50
User entered '24 Sep 2020 18:55'	System	25 Sep 2020 01:55:50

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 7'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:44', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a0b9df7e-c5c5-4acb-b0a0-b50d6a40d71f'	System	26 Sep 2020 03:57:04
User entered 'None (0)'	System	26 Sep 2020 03:57:04

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:47', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a0b9df7e-c5c5-4acb-b0a0-b50d6a40d71f'	System	26 Sep 2020 03:57:04
User entered 'None (0)'	System	26 Sep 2020 03:57:04

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:49', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a0b9df7e-c5c5-4acb-b0a0-b50d6a40d71f'	System	26 Sep 2020 03:57:04
User entered 'None (0)'	System	26 Sep 2020 03:57:04

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:51', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a0b9df7e-c5c5-4acb-b0a0-b50d6a40d71f'	System	26 Sep 2020 03:57:04
User entered 'None (0)'	System	26 Sep 2020 03:57:04

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:57:45
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:54', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a0b9df7e-c5c5-4acb-b0a0-b50d6a40d71f'	System	26 Sep 2020 03:57:04
User entered 'None (0)'	System	26 Sep 2020 03:57:04

US3642261
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:57:45
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:56', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a0b9df7e-c5c5-4acb-b0a0-b50d6a40d71f'	System	26 Sep 2020 03:57:04
User entered 'None (0)'	System	26 Sep 2020 03:57:04

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

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 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:56:59', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a0b9df7e-c5c5-4acb-b0a0-b50d6a40d71f'	System	26 Sep 2020 03:57:04
User entered 'No (N)'	System	26 Sep 2020 03:57:04

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51D0EB84-C02C-4668-B6E8-85D0FC1CC698)', Time: '2020-09-25T20:57:01', User OID: 'PatientReportedOutcome (US3642261)', ODM File OID: 'a0b9df7e-c5c5-4acb-b0a0-b50d6a40d71f'	System	26 Sep 2020 03:57:04
User entered '25 Sep 2020 20:57'	System	26 Sep 2020 03:57:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 22:14:56

US3642261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:35:21
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 22:14:56

US3642261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:52
User entered 'Yes (Y)'	Nancy Tang (b) (4)	28 Sep 2020 19:55:49

US3642261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:52
User entered '28 Sep 2020'	Nancy Tang (b) (4)	28 Sep 2020 19:55:49

US3642261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:02:52
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	28 Sep 2020 19:55:49

US3642261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:02:52
User entered empty.	Nancy Tang (b) (4)	28 Sep 2020 19:55:49

US3642261

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:02:59
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 19:56:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 19:56:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Tang (b) (4)	28 Sep 2020 19:56:00
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 19:55:55
User entered empty.	Nancy Tang (b) (4)	28 Sep 2020 19:55:55

US3642261
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:57:45
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	28 Sep 2020 19:56:00
User entered empty.	System	28 Sep 2020 19:55:55

US3642261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:03:16
User entered 'Yes (Y)'		05 Oct 2020 23:14:52

US3642261
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:03:16
User entered '5 Oct 2020'		05 Oct 2020 23:14:52

US3642261
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:03:16
User entered 'Contact Made (CONTACT MADE)'		05 Oct 2020 23:14:52

US3642261
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:03:16
User entered empty.		05 Oct 2020 23:14:52

US3642261
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:03:22
User entered 'Yes (Y)'		05 Oct 2020 23:14:58

US3642261
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:57:45
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	05 Oct 2020 23:14:58

US3642261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:03:38
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	13 Oct 2020 15:35:56

US3642261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:03:38
User entered '13 Oct 2020'	Colleen McLellan (b) (4) (b) (4)	13 Oct 2020 15:35:56

US3642261
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:03:38
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	13 Oct 2020 15:35:56
	(b) (4)	

US3642261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:03:38
User entered empty.	Colleen McLellan (b) (4) (b) (4)	13 Oct 2020 15:35:56

US3642261

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:03:43
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	13 Oct 2020 15:35:47

FDA-CBER-2022-1614-2899864

Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:57:45
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	13 Oct 2020 15:35:47

US3642261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:04:28
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	17 Oct 2020 21:17:11

FDA-CBER-2022-1614-2899866

US3642261
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:57:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:04:28
User entered '17 Oct 2020'	Megan Loughran (b) (4) (b) (4)	17 Oct 2020 21:17:11

US3642261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:04:28
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4) (b) (4)	17 Oct 2020 21:17:11

US3642261
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:57:45
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'VISIT2'	System	17 Oct 2020 21:17:11

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered 'Yes (Y)'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered '17 Oct 2020'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered '12:48'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '17 Oct 2020 12:48'	System	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered '97.8' F	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered 'Oral (Oral)'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered '55'	Son Do (b) (4)	21 Oct 2020 16:14:40

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'bpm'	System	21 Oct 2020 16:14:40

FDA-CBER-2022-1614-2899879

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered '16'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'breaths/min'	System	21 Oct 2020 16:14:40

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered '136'	Son Do (b) (4)	21 Oct 2020 16:14:40

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'mmHg'	System	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:45

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered '70'	Son Do (b) (4)	21 Oct 2020 16:14:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'mmHg'	System	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	17 Nov 2020 16:32:49
User entered 'Yes (Y)'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered empty; reason for change Data Entry Error	Colleen McLellan (b) (4) (b) (4)	17 Nov 2020 16:32:49
User entered '17 Oct 2020'	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Nov 2020 16:32:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 16:32:49
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 16:14:40
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Nov 2020 16:32:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 16:32:49
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 16:14:40
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Nov 2020 16:32:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 16:32:49
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 16:14:40
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	21 Oct 2020 16:14:40

US3642261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:45

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Nov 2020 16:32:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 16:32:49
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 16:14:40
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	21 Oct 2020 16:14:40

FDA-CBER-2022-1614-2899897

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:04:50
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Nov 2020 16:32:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 16:32:49
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 16:14:40
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

FDA-CBER-2022-1614-2899898

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	21 Oct 2020 16:14:40

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:04:50
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Nov 2020 16:32:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 16:32:49
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 16:14:40
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:14:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	21 Oct 2020 16:14:40

FDA-CBER-2022-1614-2899901

US3642261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:45

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:05:03
User entered 'Yes (Y)'	Son Do (b) (4)	21 Oct 2020 16:14:50

US3642261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:45

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:05:03
User entered '17 Oct 2020'	Son Do (b) (4)	21 Oct 2020 16:14:50

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint Verified.		19 Dec 2020 00:05:38
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:38:33
User entered 'No (N)'	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:37:32

FDA-CBER-2022-1614-2899904

US3642261
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:57:45
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User closed query 'Per CDM: As per reason subject dose withheld due to AE however no corresponding AE is seen recorded for that period.Thank you' (Site from DM).		11 Feb 2021 10:04:39
Query 'Per CDM: As per reason subject dose withheld due to AE however no corresponding AE is seen recorded for that period.Thank you' answered with 'AE log form has been completed for this event. See line 1. This occurred following the first injection, so it was decided not to give the second. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:25:22
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:05:43
User opened query 'Per CDM: As per reason subject dose withheld due to AE however no corresponding AE is seen recorded for that period.Thank you' (Site from DM).		29 Oct 2020 10:10:48
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:38:33
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:37:32

US3642261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
DataPoint Verified.		19 Dec 2020 00:05:45
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:38:33
User entered 'Subject experiencing new paresthesias and decreased sensation in her toes and ball of both feet L>R. S/P history of laminectomy in Jan 2020.'	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:37:32

US3642261
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:57:45
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	20 Oct 2020 22:37:32

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:57:45

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint Verified.		19 Dec 2020 00:05:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:38:33
User entered empty.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint Verified.		19 Dec 2020 00:05:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:38:33
User entered empty.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:37:32

US3642261
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:57:45

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	20 Oct 2020 22:37:32

US3642261
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:57:45
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint Verified.		19 Dec 2020 00:05:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:38:33
User entered empty.	Stephen Spector (b) (4) (b) (4)	20 Oct 2020 22:37:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint Verified.		19 Dec 2020 00:05:49
User entered empty.	System	20 Oct 2020 22:37:32

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:57:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	20 Oct 2020 22:37:32

US3642261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:45

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:05:56
User entered 'Yes (Y)'	Son Do (b) (4)	21 Oct 2020 16:15:01

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:05:56
User entered '17 Oct 2020'	Son Do (b) (4)	21 Oct 2020 16:15:01

FDA-CBER-2022-1614-2899915

US3642261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:05:56
User entered '14:32'	Son Do (b) (4)	21 Oct 2020 16:15:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '17 Oct 2020 14:32'	System	21 Oct 2020 16:15:01

FDA-CBER-2022-1614-2899917

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:57:45

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:06:04
User entered '17 Oct 2020'	Son Do (b) (4)	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:45

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:45

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:06:04
User entered 'Yes (Y)'	Son Do (b) (4)	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:06:04
User entered '14:34'	Son Do (b) (4)	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:45

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '17 Oct 2020 14:34'	System	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:45

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Son Do (b) (4)	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:45

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:06:04
User entered 'No (N)'	Son Do (b) (4)	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:06:04
User entered empty.	Son Do (b) (4)	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:45

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	21 Oct 2020 16:15:14

US3642261

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 00:06:07
User entered 'Yes (Y)'	Son Do (b) (4)	21 Oct 2020 16:15:18

US3642261
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:57:45
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	21 Oct 2020 16:15:18

US3642261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:30

US3642261
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:30

US3642261
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:30

US3642261

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:40

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	18 Dec 2020 21:22:40

US3642261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:06:52
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:47

US3642261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:06:52
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 21:22:47
	(b) (4)	

US3642261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:06:52
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:47

US3642261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 00:06:52
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:47

US3642261

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:22:51

US3642261

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	18 Dec 2020 21:22:51

US3642261
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:20

US3642261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:20

US3642261
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:20

US3642261
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:20

US3642261

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:25

US3642261
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:57:45
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	18 Dec 2020 21:23:25

Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:57:45

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:34

US3642261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:34

US3642261
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:57:45
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered 'VISIT3'	System	18 Dec 2020 21:23:34

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:23:41

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

US3642261
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

US3642261
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

US3642261
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:23:41

US3642261
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:57:45
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:23:41

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:23:41

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:23:41

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:45

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:47

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:47

US3642261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:45

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:52

US3642261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:45

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:52

US3642261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:45

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:23:52

US3642261

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:23:56

US3642261
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:57:45
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	18 Dec 2020 21:23:56

US3642261
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23
Data entry locked.	System	19 Sep 2020 22:14:56
User entered 'Day 64'	System	19 Sep 2020 22:14:56

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23
Data entry locked.	System	19 Sep 2020 22:14:56
User entered '19 Nov 2020 00:01'	System	19 Sep 2020 22:14:56

FDA-CBER-2022-1614-2900002

US3642261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:50:23
Data entry locked.	System	19 Sep 2020 22:14:56
User entered '23 Nov 2020 23:59'	System	19 Sep 2020 22:14:56

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:50:23

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

FDA-CBER-2022-1614-2900008

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

FDA-CBER-2022-1614-2900028

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 09:50:23

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 09:50:23

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:50:23

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 09:50:23

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 09:50:23

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:50:23

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

FDA-CBER-2022-1614-2900065

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 09:50:23

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 09:50:23

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:50:23

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

FDA-CBER-2022-1614-2900092

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

FDA-CBER-2022-1614-2900112

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 09:50:23

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 09:50:23

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:50:23

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

FDA-CBER-2022-1614-2900126

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

FDA-CBER-2022-1614-2900132

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

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)	26 Apr 2021 20:43:55

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Please 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)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:57:45
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 09:50:23

US3642261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:45

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:50:23
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 09:50:23

US3642261
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:57:45

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Nancy Tang (b) (4)	18 Dec 2020 23:40:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '18 Dec 2020'	Nancy Tang (b) (4)	18 Dec 2020 23:40:37

FDA-CBER-2022-1614-2900145

US3642261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	18 Dec 2020 23:40:37

US3642261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:45

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	18 Dec 2020 23:40:37

US3642261

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:45

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Nancy Tang (b) (4)	18 Dec 2020 23:40:44

US3642261
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:57:45
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	18 Dec 2020 23:40:44

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:34:00
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4) (b) (4)	30 Mar 2021 17:02:16
User entered '26 Dec 2020'	Son Do (b) (4)	29 Mar 2021 22:16:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:34:00
User entered '1' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	30 Mar 2021 17:02:16
User entered '0'	Son Do (b) (4)	29 Mar 2021 22:16:17

FDA-CBER-2022-1614-2900151

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:34:00
User entered 'Yes (Y)'	Son Do (b) (4)	29 Mar 2021 22:16:17

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:34:00
User entered 'Amendment 5 (Amendment 5)'	Son Do (b) (4)	29 Mar 2021 22:16:17

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:34:00
User entered '26 Dec 2020'	Son Do (b) (4)	29 Mar 2021 22:16:17

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:34:00
User entered 'Placebo (Placebo)'	Son Do (b) (4)	29 Mar 2021 22:16:17

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:34:00
User entered 'Placebo (Placebo)'	Son Do (b) (4)	29 Mar 2021 22:16:17

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:34:00
User entered 'Not Administered (NA)'	Son Do (b) (4)	29 Mar 2021 22:16:17

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:34:00
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	30 Mar 2021 17:02:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Son Do (b) (4)	30 Mar 2021 15:29:23
User entered 'No (N)'	Son Do (b) (4)	29 Mar 2021 22:16:17

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	29 Mar 2021 22:16:17

US3642261

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:45

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	30 Mar 2021 17:02:16
User entered '1'	System	30 Mar 2021 15:29:23
User entered empty.	System	29 Mar 2021 22:16:17

US3642261

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:57:45

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Tang (b) (4)	24 Nov 2020 02:27:16
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:56:57

US3642261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

US3642261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Paraesthesia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:07:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:07:16
Data point term sent to Coder	System	10 Dec 2020 18:02:45
Query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:01:50
User opened query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	27 Nov 2020 00:35:14
Data point term sent to Coder	System	25 Nov 2020 17:48:38
User entered 'Decrease in sensation and Paresthesia'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '03 Oct 2020'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	25 Nov 2020 17:48:05

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:57:45

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

FDA-CBER-2022-1614-2900174

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:57:45

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	(b) (4) Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Related (RELATED)'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Not Related (NOT RELATED)'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per CDM: Please complete 'Dosing Discontinuation' form. Thank you' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:00:08
Query 'Per CDM: Please complete 'Dosing Discontinuation' form. Thank you' answered with 'form completed' (Site from DM).	Megan Loughran (b) (4) (b) (4)	10 Dec 2020 23:40:46
User opened query 'Per CDM: Please complete 'Dosing Discontinuation' form. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 18:01:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '1'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Subject reports decrease in sensation and paresthesias. Vaccine #2 Investigational product not given. Subject diagnosed with soft tissue bunionette by primary care physician. Subject will continue to remain on study.'	Nancy Tang (b) (4)	25 Nov 2020 17:48:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:45

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '0'	System	25 Nov 2020 17:48:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	25 Nov 2020 17:48:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User closed query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM).		08 Apr 2021 04:43:24
Query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' answered with 'cm 10' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	07 Apr 2021 18:34:13
User opened query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 16:55:35
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 17:55:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
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) (b) (4)	18 Dec 2020 21:03:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:03:51
Data point term sent to Coder	System	18 Dec 2020 21:03:15
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:02:29
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) (b) (4)	01 Oct 2020 17:57:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 17:57:00
Data point term sent to Coder	System	01 Oct 2020 17:56:27
User entered 'flu vaccine'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 04:21:16
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:03:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:02:29
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:51:55
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'prophylaxis for flu' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:02:29
User entered 'vaccine'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0.5' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:02:29
User entered '1'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'mL (mL)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:02:29
User entered 'Other (OTHER)'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:02:29
User entered 'injection'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'once (ONCE)'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Intramuscular (INTRAMUSCULAR)'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '01 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:56:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 17:56:16

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:56:16

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '01 Sep 2020'	Son Do (b) (4)	01 Oct 2020 17:56:16

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:56:16

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:56:16

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:56:16

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 17:56:16

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:06:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:06:01
Data point term sent to Coder	System	01 Oct 2020 18:01:40
User entered 'multi vitamin'	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 04:21:24
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:03:15
User entered 'Yes (Y)' reason for change: Per Query Resolution	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:03:12
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:52:13
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'supplement'	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '1'	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'tablet (TABLET)'	Son Do (b) (4)	01 Oct 2020 18:00:43

FDA-CBER-2022-1614-2900221

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'once daily (QD)'	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Oral (ORAL)'	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '02 Aug 2019'	Son Do (b) (4)	01 Oct 2020 18:00:43

FDA-CBER-2022-1614-2900227

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 18:00:43

FDA-CBER-2022-1614-2900228

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '804 (804)'	System	01 Oct 2020 18:00:43

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 21:32:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 21:32:37
Data point term sent to Coder	System	09 Feb 2021 21:31:39
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:31:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:07:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:07:30
Data point term sent to Coder	System	01 Oct 2020 18:02:43
User entered 'vitamin d3'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'vitamin d DEFICIENCY' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:31:15
User entered 'deficiency'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '5000'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'IU (IU)'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'once daily (QD)'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Oral (ORAL)'	Son Do (b) (4)	01 Oct 2020 18:01:44

FDA-CBER-2022-1614-2900243

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'UN Jul 2019'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
User entered '0'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:01:44

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '804 (804)'	System	01 Oct 2020 18:01:44

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: MONASCUS PURPUREUS, PRODUCTSYNONYM: RED YEAST RICE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 04:41:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 04:41:51
Data point term sent to Coder	System	16 Oct 2020 21:06:32
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:05:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: MONASCUS PURPUREUS, PRODUCTSYNONYM: RED YEAST RICE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:15:42
Data point term sent to Coder	System	01 Oct 2020 18:02:43
User entered 'red rice yeast'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 04:21:44
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:03:27
User entered 'Yes (Y)' reason for change: Per Query Resolution	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:03:24
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:52:52
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:02:21

FDA-CBER-2022-1614-2900254

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Supplement for HIGH CHOLESTEROL' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	16 Oct 2020 21:05:34
User entered 'high cholesterol'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '1'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'tablet (TABLET)'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'once daily (QD)'	Son Do (b) (4)	01 Oct 2020 18:02:21

FDA-CBER-2022-1614-2900259

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Oral (ORAL)'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'UN Jul 2019'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '804 (804)'	System	01 Oct 2020 18:02:21

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:07:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:07:22
Data point term sent to Coder	System	18 Dec 2020 21:05:16
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:04:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:08:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:08:21
Data point term sent to Coder	System	01 Oct 2020 18:03:45
User entered 'naproxen'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Indication

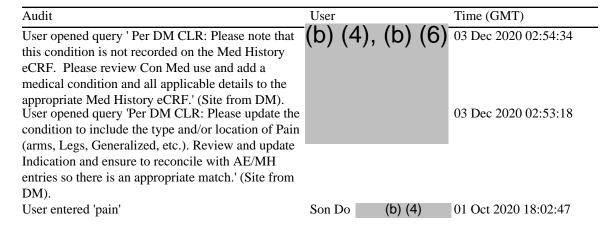| Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per DM CLR re-query: Response noted. However, please reconcile and update the 'condition' / 'dates' in Medical history form for the appropriate match.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 03:46:39
Query 'Per DM CLR re-query: Response noted. However, please reconcile and update the 'condition' / 'dates' in Medical history form for the appropriate match.' answered with 'mh has been updated' (Site from DM).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:32:50
User opened query 'Per DM CLR re-query: Response noted. However, please reconcile and update the 'condition' / 'dates' in Medical history form for the appropriate match.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 05:43:39
User closed query ' Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).		21 Dec 2020 05:42:43
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).		21 Dec 2020 04:23:49
Query ' Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:04:45
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:04:42
User entered 'back pain' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:04:38

FDA-CBER-2022-1614-2900273

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
User opened query ' Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:54:34
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).		03 Dec 2020 02:53:18
User entered 'pain'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '500'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'mg (mg)'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'as needed (PRN)'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Oral (ORAL)'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'UN UNK 2017'	Son Do (b) (4)	01 Oct 2020 18:02:47

FDA-CBER-2022-1614-2900282

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 18:02:47

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:57:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	01 Oct 2020 18:02:47

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 22:12:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 22:12:49
Data point term sent to Coder	System	18 Dec 2020 21:08:20
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:08:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 05:24:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 05:24:45
Data point term sent to Coder	System	01 Oct 2020 18:04:48
User entered 'furosemide'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query ' Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 04:28:32
Query ' Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:08:20
User entered 'dependent edema' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:08:16
User opened query ' Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:54:48
User entered 'constipation'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '10'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'mg (mg)'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'once daily (QD)'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:04:31

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Oral (ORAL)'	Son Do (b) (4)	01 Oct 2020 18:04:31

FDA-CBER-2022-1614-2900298

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '23 Feb 2019'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'Yes (Y)'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	01 Oct 2020 18:04:31

FDA-CBER-2022-1614-2900305

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	01 Oct 2020 18:04:31

FDA-CBER-2022-1614-2900306

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '804 (804)'	System	01 Oct 2020 18:04:31

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 07:59:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 07:59:04
Data point term sent to Coder	System	25 Nov 2020 17:53:41
User entered 'MethylPREDNISolone (Medrol DOSEPACK)'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

FDA-CBER-2022-1614-2900308

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 03:38:14
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'data are correct. participant was prescribed this medication by ED provider when she presented for assessment of decrease of sensation. ' (Site from DM).	Megan Loughran (b) (4)	09 Feb 2021 21:50:31
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 03:42:52
User entered 'Decrease in sensation and paresthesia'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered '4'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'mg (mg)'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per DM CLR: Please review frequency as this was not given once per "ONGOING" dates. Either update frequency or update start/end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 03:40:44
Query 'Per DM CLR: Please review frequency as this was not given once per "ONGOING" dates. Either update frequency or update start/end date. Else, clarify.' answered with 'revised ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:50:01
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	09 Feb 2021 21:49:48
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	09 Feb 2021 21:49:48
User entered 'once daily (QD)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:49:48
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	09 Feb 2021 21:49:31
User opened query 'Per DM CLR: Please review frequency as this was not given once per "ONGOING" dates. Either update frequency or update start/end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 03:43:01
User entered 'once (ONCE)'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

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US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '18 Oct 2020' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 22:06:32
User entered '17 Oct 2020' reason for change: Data Entry Error	Nancy Tang (b) (4)	25 Nov 2020 17:54:43
User entered '03 Oct 2020'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:49:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 22:06:49
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 22:06:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Tang (b) (4)	25 Nov 2020 17:55:28
User entered 'No (N)' reason for change: Data Entry Error	Nancy Tang (b) (4)	25 Nov 2020 17:55:03
User entered 'Yes (Y)'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

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US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '23 Oct 2020' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:49:31
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 22:06:49
User entered '18 Oct 2020' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 22:06:32
User entered empty; reason for change Data Entry Error	Nancy Tang (b) (4)	25 Nov 2020 17:55:28
User entered '17 Oct 2020' reason for change: Data Entry Error	Nancy Tang (b) (4)	25 Nov 2020 17:55:03
User entered empty.	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

FDA-CBER-2022-1614-2900321

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Nancy Tang (b) (4)	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	09 Feb 2021 21:49:48
User entered empty.	System	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '1'	System	09 Feb 2021 21:49:48
User entered empty.	System	25 Nov 2020 17:53:19

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered '804 (804)'	System	09 Feb 2021 21:49:48
User entered empty.	System	25 Nov 2020 17:53:19

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CIGARETTE SMOKER; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 03:42:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 21:44:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 21:44:39
Data point term sent to Coder	System	09 Feb 2021 21:43:50
Coding entries removed.	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:42:58
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CIGARETTE SMOKER; update Con Med indication or provide clarification. ' answered with 'there is no worsening of medical condition. participant decided to pursue supportive treatment to help with smoking cessation. no ae is required. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:42:39
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CIGARETTE SMOKER; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 03:43:24

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:35:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 21:35:09
Data point term sent to Coder	System	18 Dec 2020 21:32:57
User entered 'chantix'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:42:58
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per DM CLR: After reviewing if this medication was added because the patient's medical history condition worsened, please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update the indication if applicable or please clarify. If a condition is added to the indication please ensure the MH/ AE eCRF are updated accordingly and review if the prophylaxis indication should be changed as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 03:43:34
Query 'Per DM CLR: After reviewing if this medication was added because the patient's medical history condition worsened, please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update the indication if applicable or please clarify. If a condition is added to the indication please ensure the MH/ AE eCRF are updated accordingly and review if the prophylaxis indication should be changed as appropriate.' answered with 'condition is already listed on mh. indication updated to remove prophylaxis. this is not a worsening of an ongoing condition. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:44:30
User entered 'CIGARETTE SMOKer' reason for change: Per Query Resolution	Megan Loughran (b) (4) (b) (4)	09 Feb 2021 21:42:58
User opened query 'Per DM CLR: After reviewing if this medication was added because the patient's medical history condition worsened, please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update the indication if applicable or please clarify. If a condition is added to the indication please ensure the MH/ AE eCRF are updated accordingly and review if the prophylaxis indication should be changed as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 03:43:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
User entered 'prophylaxis for cigarette smoking'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0.5'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '17 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '17 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 21:32:38

FDA-CBER-2022-1614-2900342

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	18 Dec 2020 21:32:38

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:33:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:33:33
Data point term sent to Coder	System	06 Apr 2021 19:43:40
User entered 'MODERNA COVID-19 VACCINE (EXTERNAL)'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered 'COVID-19 PROPHYLAXIS'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered '0.5'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered 'mL (mL)'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered empty.	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered 'once (ONCE)'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered empty.	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered 'Intramuscular (INTRAMUSCULAR)'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered empty.	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered '27 Dec 2020'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered '0'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered '27 Dec 2020'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	06 Apr 2021 19:42:52

US3642261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	06 Apr 2021 19:42:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User entered empty.	System	06 Apr 2021 19:42:52

FDA-CBER-2022-1614-2900363

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:57:45

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
User entered 'No (N)'	Son Do (b) (4)	01 Oct 2020 17:55:32

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:57:45

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 18:28:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:49
User entered '17 Oct 2020'	Megan Loughran (b) (4)	10 Dec 2020 23:40:04
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:57:45

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:49
User entered 'AE (specify) (ADVERSE EVENT)'	Megan Loughran (b) (4) (b) (4)	10 Dec 2020 23:40:04

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Mar 2021 02:23:27
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 10:42:06
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'UPDATED PER REQUEST' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	10 Mar 2021 13:14:06
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	10 Mar 2021 13:13:59
User entered 'AE # 1' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	10 Mar 2021 13:13:59
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:10:12
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 12:49:29
Query 'Per CDM: Please record AE record number instead of details ' answered with 'AE LOG LINE 1' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	02 Feb 2021 23:57:01
DataPoint Un-verified.	Colleen McLellan (b) (4) (b) (4)	02 Feb 2021 23:56:57
User entered 'AE LOG LINE 1' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	02 Feb 2021 23:56:57
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 12:41:53
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 23:53:49
User entered 'DECREASE IN SENSATION AND PARESTHESIA' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	10 Dec 2020 23:40:36
User entered 'tingling/numbness in feet'	Megan Loughran (b) (4) (b) (4)	10 Dec 2020 23:40:04

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:45

Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered '27 Dec 2020'	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 17:14:36

US3642261

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:45

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User closed query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' (Site from DM).		15 Apr 2021 16:15:31
Query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' answered with 'participant received non study vaccine prior to withdrawal. protocol deviation has been selected. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	13 Apr 2021 21:15:32
User opened query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 17:13:36
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	09 Apr 2021 00:00:51
User closed query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:35:27
Query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' answered with 'UPDATED REASON FOR DISCONTINUATION PER REQUEST' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:41:51
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:41:43
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 19:41:43

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:45

Reason for discontinuation

Audit	User	Time (GMT)
User opened query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 16:56:03
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'Other (OTHER)'	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 17:14:36

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered 'PARTICIPANT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY THROUGH EUA'	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 17:14:36

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:45

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 17:14:36

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:45

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 17:14:36

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:45

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 17:14:36

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:43:55
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 18:28:36
User entered empty.	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 17:14:36

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